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Award Number: DAMD17-02-C-0070

TITLE: Patient-Clinician Encounter Information Modeling Through Web Based Intelligent 3D Visual Interfaces

PRINCIPAL INVESTIGATOR: Jerzy Bala, Ph.D.
Peter Pachowicz

CONTRACTING ORGANIZATION: Sigma Systems Research, Incorporated
Fairfax, Virginia 22032

REPORT DATE: September 2002

TYPE OF REPORT: Final, Phase I

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

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20021024 055

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 074-0188

1. AGENCY USE ONLY (Leave blank)	2. REPORT DATE	3. REPORT TYPE AND DATES COVERED
	September 2002	Final, Phase I (15 Feb 02 - 15 Aug 02)

4. TITLE AND SUBTITLE
Patient-Clinician Encounter Information Modeling Through Web Based Intelligent 3D Visual Interfaces

5. FUNDING NUMBERS
DAMD17-02-C-0070

6. AUTHOR(S)
Jerzy Bala, Ph.D.
Peter Pachowicz

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
Sigma Systems Research, Incorporated
Fairfax, Virginia 22032

Email: jbala@sigma-sys.com

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSORING / MONITORING AGENCY REPORT NUMBER

11. SUPPLEMENTARY NOTES
report contains color

PROPRIETARY INFORMATION; Sep 2002

12a. DISTRIBUTION / AVAILABILITY STATEMENT
Distribution authorized to U.S. Government agencies only ~~(specific authority)~~. Other requests for this document shall be referred to U.S. Army Medical Research and Materiel Command, 504 Scott Street, Fort Detrick, Maryland 21702-5012.

12b. DISTRIBUTION CODE

13. ABSTRACT *(Maximum 200 words)*

This Phase I Small Business Innovative Research (SBIR) project was concerned with the development of medical information access and presentation technology. The project has developed and initially implemented BetterView, a specific approach for medical data visualization and browsing. The approach supports (a) high-level exploration and interaction with medical information through advanced 3D visualization, (b) presentation of a Gestalt view of the patient to the clinician (i.e., the "Big Picture" presentation that facilities more cooperative, and thereby intelligent, reasoning between clinicians and patients' data models and more cognitive presentation of clinical data), (c) direction of the clinician to the most plausible diagnostic hypotheses very early in the process of information exploration, and (d) information access at a higher level of abstraction (to free the physicians to focus on issues that matter the most instead of on details and system functions that don't). During the Phase I effort, commercial potentials of the developed technology have been identified. Commercialization will be initially pursued with the Department of Defense (e.g., TRICARE - a healthcare program for military families and retirees). This technology should also be of interest to those HMO type healthcare provider commercial sectors that encompass a full range of services from outpatient primary care in remote clinics to intensive care within large teaching medical centers.

14. SUBJECT TERMS	15. NUMBER OF PAGES
adaptive interfaces, 3D visualization, patient-clinician encounter modeling, intelligent interfaces	44
	16. PRICE CODE

17. SECURITY CLASSIFICATION OF REPORT	18. SECURITY CLASSIFICATION OF THIS PAGE	19. SECURITY CLASSIFICATION OF ABSTRACT	20. LIMITATION OF ABSTRACT
Unclassified	Unclassified	Unclassified	Unlimited

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Project Abstract

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During the Phase I effort, commercial potentials of the developed technology have been identified. Commercialization will be initially pursued with the Department of Defense (e.g., TRICARE - a healthcare program for military families and retirees). This technology should also be of interest to those HMO type healthcare provider commercial sectors that encompass a full range of services from outpatient primary care in remote clinics to intensive care within large teaching medical centers.

1.0 Introduction

Nothing tends so much to the advancement of knowledge as the application of a new instrument. The native intellectual powers of men in different times are not so much the causes of the different success of their labours, as the peculiar nature of the means and artificial resources in their possession.

- Sir Humphrey Davy

1.1 Motivations

A clinician reasons about individual patients on the basis of analogy, experience, heuristics, and theory as well as research evidence. This reasoning process is supported by diverse and emerging clinical data sources. As the amount of this data explodes, clinicians are faced with the difficult task of analyzing it (e.g., sifting the data into meaningful diagnostic groups). To challenge this information explosion problem, the clinical data sets must be condensed to more meaningful and accurate spatial-temporal representations of a patient's conditions to reinforce diagnostically optimal outcomes of patient-clinician encounter episodes. These representations shall (1) support evidence-based diagnosis process, (2) be accessible via Web browsers, (3) be cognitively oriented, (4) must be "event driven" (e.g., if the clinician is evaluating some diagnostic hypothesis from some portion of the data and needs to look up the lab data, the system must allow immediate access to the lab data without the need to abort the evaluation process), and (5) must apply visual thinking principles.

It was an assumption from the very beginning of the Phase I project that such meaningful condensed representations can follow the **Gestalt principle** conventions of: (a) assigning diagnostic importance based on informational/content contrast to determine if the information is worthy (e.g., a series of contrasting x-ray images to capture attention), (b) chunking information content based on repetitive visual clues (e.g., repetition of similar lab test results imposes a diagnostic structure), (c) displaying a hierarchy of data components based on alignment (alignment creates patterns and helps to separate significant from irrelevant data), (d) presenting related information together, and (e) connecting initially unrelated information as results of proximity (proximity can help in integrating all available information to form a singular contextual representation). Development of such Gestalt based presentation techniques is not an easy task since the rules for organizing the data to more holistically oriented presentations are not well defined at the present time.

Some solutions to the medical data display problem can be drawn from the area of intelligent interactive interfaces. Intelligent interactivity has become an important requirement for human-machine interfacing. Lack of interactivity is evident in the interface's inability to capture the user's model of interactions. For example, in most of the current clinical data presentation systems, only the clinician does any modeling or remembering of the interaction and its parts. The clinician's goals and tasks lie completely outside of the interface and the human-machine interaction is largely a one-way activity of commending the system and receiving pre-wired responses (i.e., presentation template). Whatever role the machine interface has played in the interaction, it completely forgets its activities when it completes the action requested. Capturing and modeling this level of interaction, and specifically constructing dialogue-based interaction, user models, and discourse models, is a minimum requirement for the intelligent interfaces.

Another problem affecting interface interactivity is a lack of general mechanisms for interpreting input from multiple data sources to automatically generate coordinated multimedia presentations.

Following the above observations, the objective of the Phase I effort was to develop a Gestalt based medical information visualization approach that would explore (a) 3D visualization interface techniques, (b) exhibit a mechanism of intelligent interactivity by incorporating adaptive patient encounter modeling as well as machine reasoning about the immediate information needs of clinicians, and (c) implement a component based and Web enabled software tool. Figure 1 illustrates a high level view of the major components of the developed approach in Phase I.

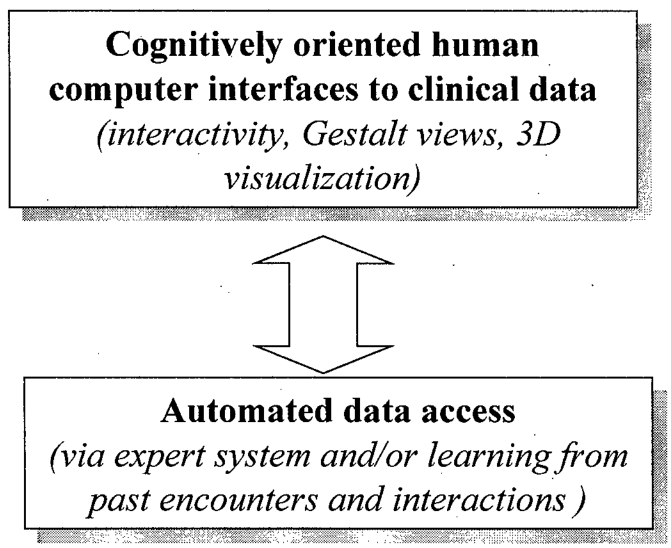

Figure 1. The two major elements of the developed medical data visualization approach

1.2 Major Phase I Accomplishments

The major project Phase accomplishments are listed below:

- Development of the *BetterView* information approach that synergistically integrates 3D visualization within the presentation interface,
- Implementation of an experimental prototype version of *BetterView* (Figure 2).
- Incorporation of a specific diagnostic scenario within the implemented prototype,
- Thorough investigation of current methods for information presentation for patient-clinician encounter modeling,
- Identification of the commercial partners and securing a substantial level of contributions and in-kind support for the Phase II effort, and
- User feedback collection (*BetterView* has been demonstrated: at the American Telemedicine Association's Annual Meeting and Exposition in Los Angeles, to a group of physicians of the Loudoun County Hospital, and at the Integrated Product Review meeting to a group of medical specialists at WRAIR/TATRC),

- The Phase I project has assembled a high impact development team. The team involves a medical Subject Matter Expert; Shirin Trachiotis, M.D. Dr. Trachiotis served as a consultant on the project. She is a member of National Board of Medical Examiners, PALS, ACLS certified. She is an attending physician with the emergency medicine group at the Holy Cross Hospital (Silver Spring, MD). Two commercialization partners have been included within the project team; Information Pathwaves, Inc. (IPI) and Tecmasters Inc. They will both contribute in Phase II a substantial in-kind support to the project development (multimedia and 3D visualization expertise) and commercialization (business development expertise) activities.

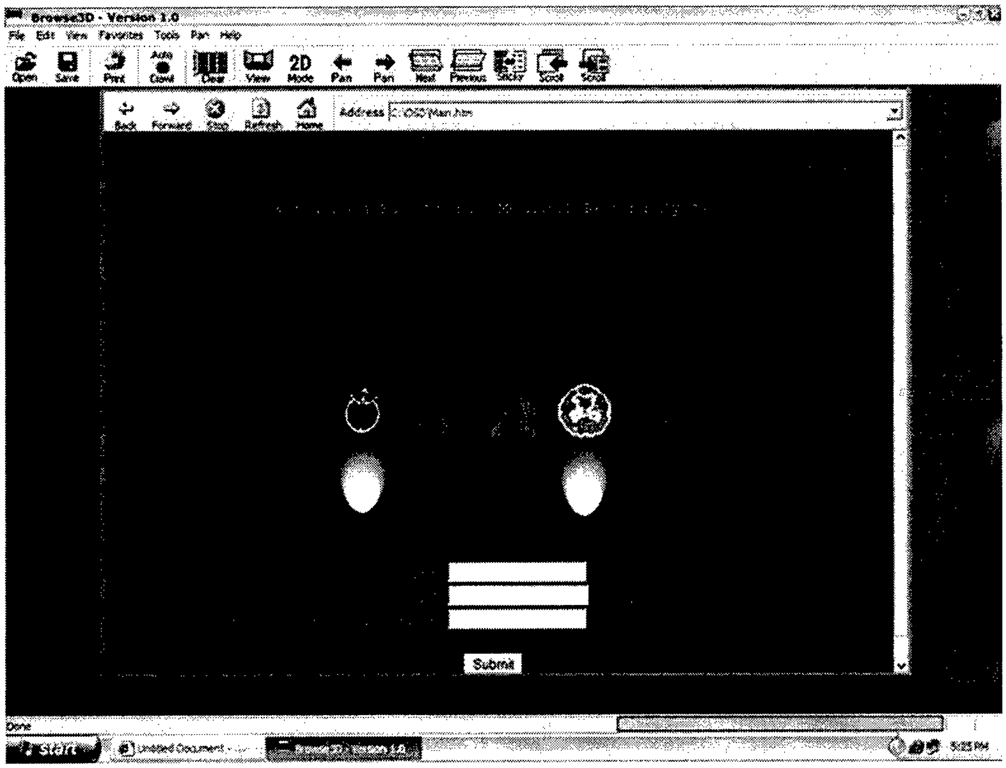

Figure 2. A *BetterView* main screen

2.0 The Technology

2.1 Major Requirement

The goal of the clinical data presentation system is to facilitate the dialogue between the clinician and the computer system by bridging their apparent conceptual gaps using communication alignment at the semantic, pragmatic and motivational level[1]. Achieving this alignment process requires incorporation of some level of automation and/or system level reasoning. This could be accomplished by the use of an expert system approach. However, a myriad of diagnostic reasoning methods (e.g., exhaustive, pattern recognition, algorithmic, probabilistic reasoning, hypothetico-deductive) makes it difficult to develop a universal expert system approach that could account for all patient-clinician diagnostic interactions. In addition, the massiveness of data precludes efficient handcrafting of the expert system knowledge base and makes it difficult to present and interpret input from multiple and temporal data sources (clinician's ability to reason does not scale up to the amount of patient's data).

To challenge this clinical data presentation problem, we need new tools that encompass a broad range of functional capabilities, from automatic data request generation techniques to advanced and state-of-the-art data visualizations. These new techniques should greatly speed up the clinician' ability to access and integrate information. Examples of such techniques include:

- Gestalt based information presentation techniques,
- Techniques incorporating cognitive aspects of exploitation processes (e.g., assessing meaning, separating significant from irrelevant data, and integrating all available data to form analytical context), and
- Task management and interfacing techniques (e.g., mechanisms for efficiently dividing diagnostic process tasks between the clinician and the computational display system).

The above list of examples was a starting point for the identification of the *BetterView* system functional capabilities. The next subsection describes these system functionalities.

[1] Semantic alignment is usually the only alignment current systems use, and even this is done only to a limited extent. The proposed approach, in its long-term goal, goes beyond semantic alignment and would assess clinician's pragmatics using decision-making tools and uncertainty analysis. Both clinician's pragmatics, motivations and beliefs can then further facilitate the semantic alignment process as they provide meaningful feedback to the overall patient encounter process.

2.2 Functional Capabilities

During the Phase I developmental effort various functional capabilities have been identified. Some of them were implemented and demonstrated in Phase I, and some will be pursued in the future (i.e., mainly via Phase II if awarded for further development under the SBIR program):

- Support for the high-level exploration and interaction with medical information,
- Support for the presentation of a Gestalt view of a patient to a clinician (i.e. visually fused and interactive descriptions will form a "Big Picture" that will be easier to comprehend),
- Direct the clinician to the most plausible diagnostic hypotheses very early in the process of information exploration,
- Provide information at a higher level of abstraction, and free the physicians to focus on issues that matter the most instead of on details and system functions that don't,
- Reveal new indicators, issues, and/or clinical threats that would not have been found otherwise due to the massiveness of the data (i.e., the data size, as well as, its numerous types and formats generated by various medical modalities),
- Identify structures within medical data to generate novel and plausible explanations for those structures,
- Help in evaluation of those structures and track their plausibility as more diagnostic data is presented, and
- Help with tracking evidence related to multiple chains of reasoning (making it easy to recognize and simultaneously evaluate multiple alternatives).
- Displaying correlated information (hypertension vs. medication, hypertension vs. some other condition, family history, social conditions, etc),
- Learning from the historical data and the clinician interactions and/or incorporating an expert system approach to automate data presentation and interactions,
- Incorporation of a set of generic functional capabilities and an extended set of capabilities, tailored for a specific group of clinicians,
- The use of a highly interactive graphical interface based on the application of Java 3D and OpenGL visualization standards, and
- Incorporation of the capability to interface with a variety of Computer Patient Records (CPR) data interface layers.

The above list gave birth to the identification of the following system level functional components (they have been initially implemented in Phase I and are described in the next sections):

- Data representation component,
- Data display and browsing component,
- 3D visualization component, and
- Data request modeling component.

2.3 Data Representation Component

The data structures generated by the data representation component are used by the *BetterView* data display component. The representation component selects data types (e.g., blood test report, MRI imagery) and their generality level. The generality level is defined by the following two data layers (Figure 3):

- General Data Layer: This layer can be seen as the container of general data components, of various types, associated with a given patient and requested during the first patient-clinician encounter episode (i.e., usually requested by a general practitioner) and
- Specific Data Layer: This is a container for data requests resulting from a specific set of tests (i.e., usually requested by a medical specialist).

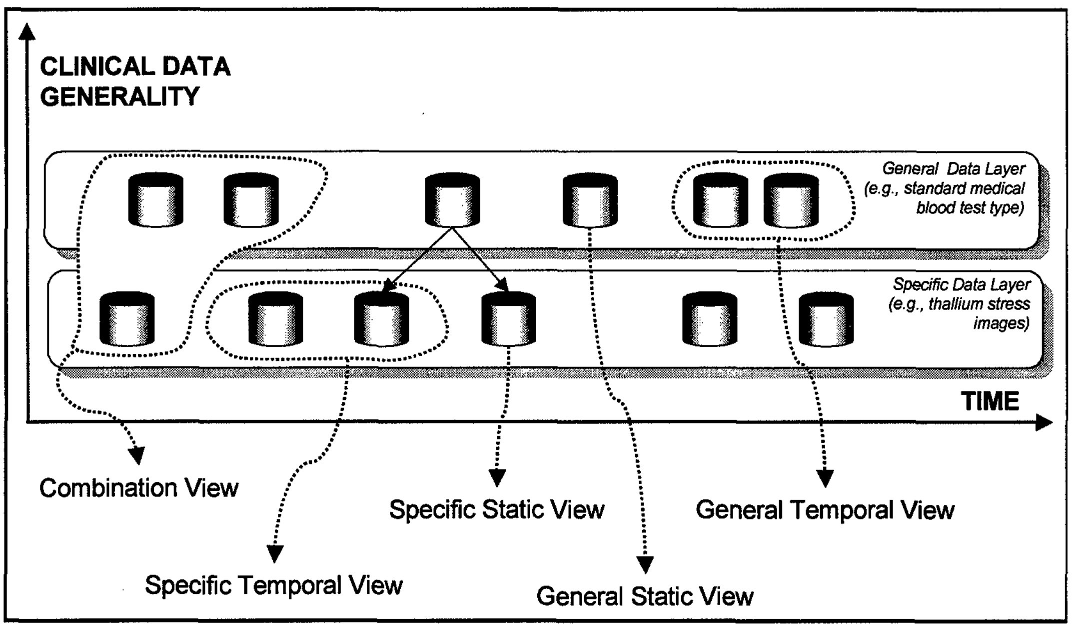

Figure 3. Five different data views generated from two data layers

As illustrated in Figure 3, the following aggregated views can be generated using this two-layer data structure:

- General Static View: This view is generated from a single data component,
- General Temporal View: This view is generated using multiple data components originating from different time frames,
- Specific Static View: Generation of this view requires access to specific clinical data components (e.g., specific imagery data),
- Specific Temporal View: Similarly to the general temporal view, this view displays multiple specific data components, and
- Combination View: This view combines elements of the above views. When properly fused the combination views could server as Gestalt presentations.

The data layered representation can be extended to a tree-like data structure (Figure 4). A node in the tree structure constitutes an elementary presentational component. The node is also characterized by a set of attributes that represents metadata information about views and data associated with this node. The view/data tree structure is a starting point for generation of aggregated data views. This is accomplished by analyzing the metadata information about existing nodes and linking a subset of them that satisfy the attribute-weighting schema (e.g., aggregating the most frequent encounters within some time window). The linked nodes can now be fused to form a new presentation node (Figure 5).

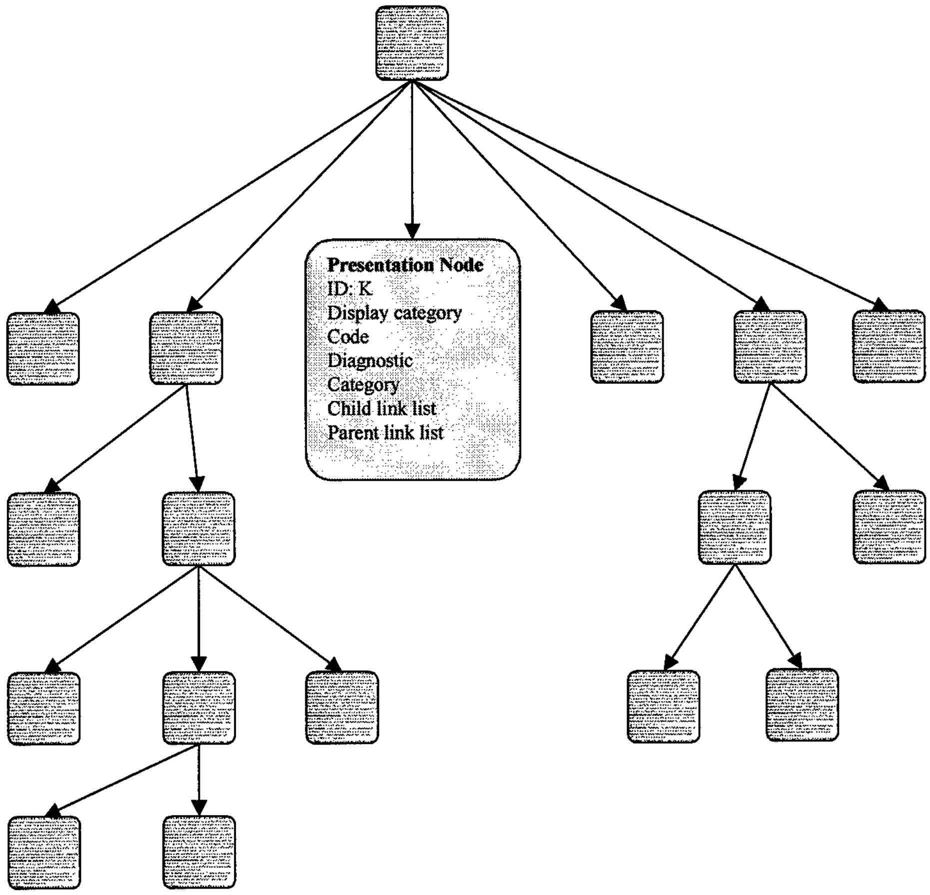

Figure 4. A five-layer tree data structure

The node attribute-weighting schema is based on clinically relevant and/or expected data presentation requests associated with a set of diagnostic scenarios. The following are just few examples of weighting schemas:

- By encounter frequency,
- By symptom type,
- By symptom severity,
- By lab result history, and
- By radiological imagery history.

New nodes generated from the original tree structure can be combined and attached to the tree (Figure 6). Figure 7 depicts generation of an ECG aggregated view (at the file level data structure). This example is taken from the Phase I demo. Three ECG views are available in three different nodes and are aggregated to a new presentation node.

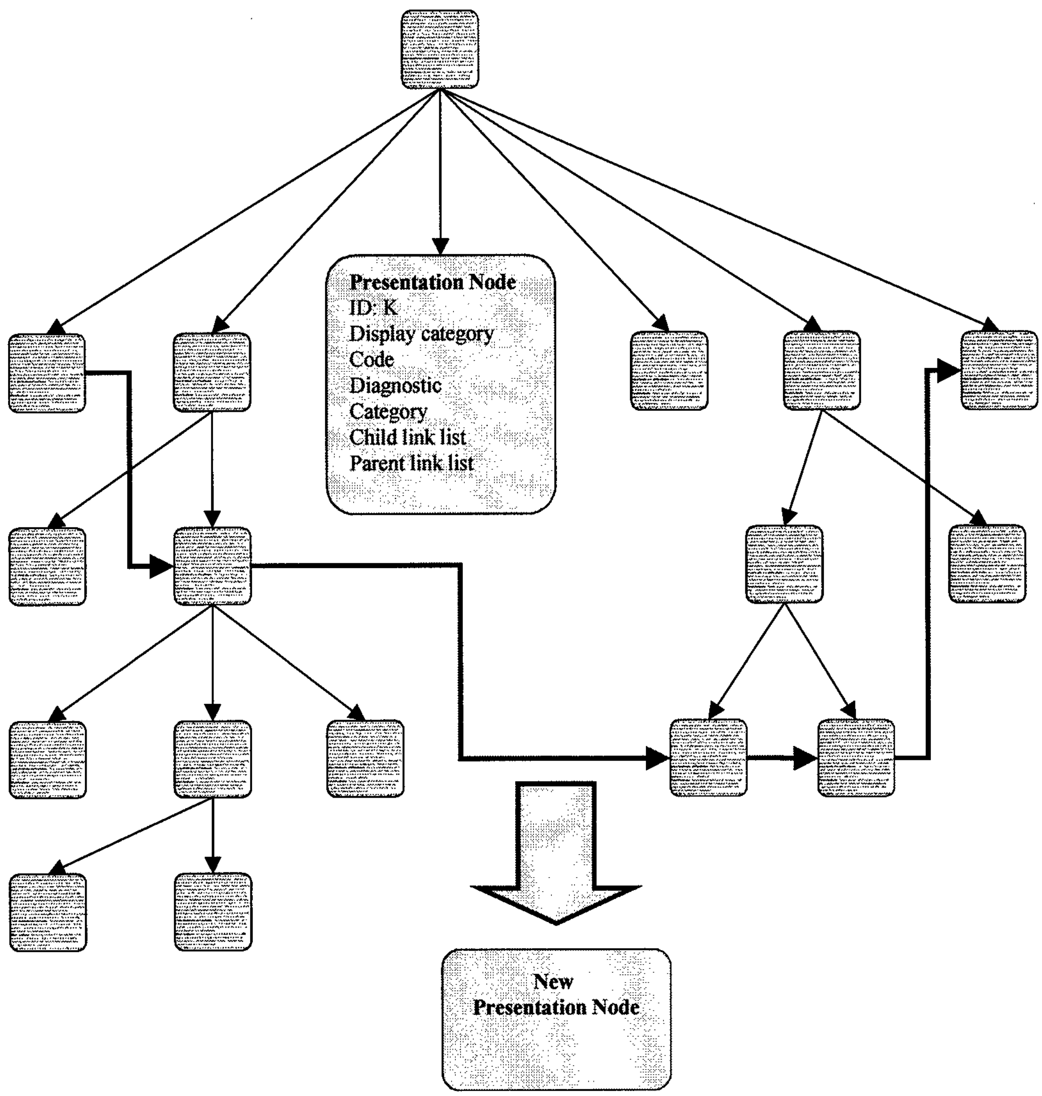

Figure 5. Generation of a new presentation node

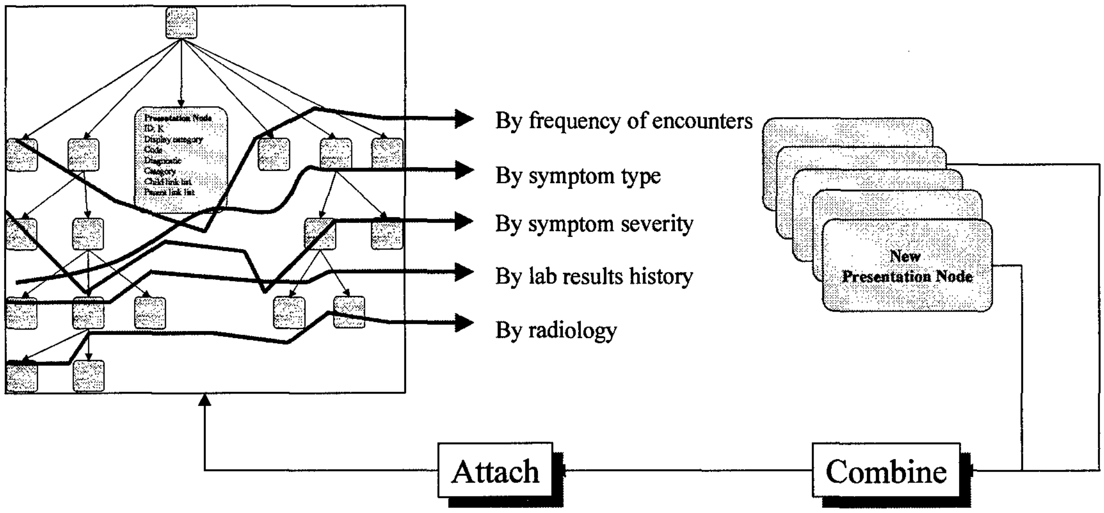

Figure 6. New presentation node generation using different weighting schemas

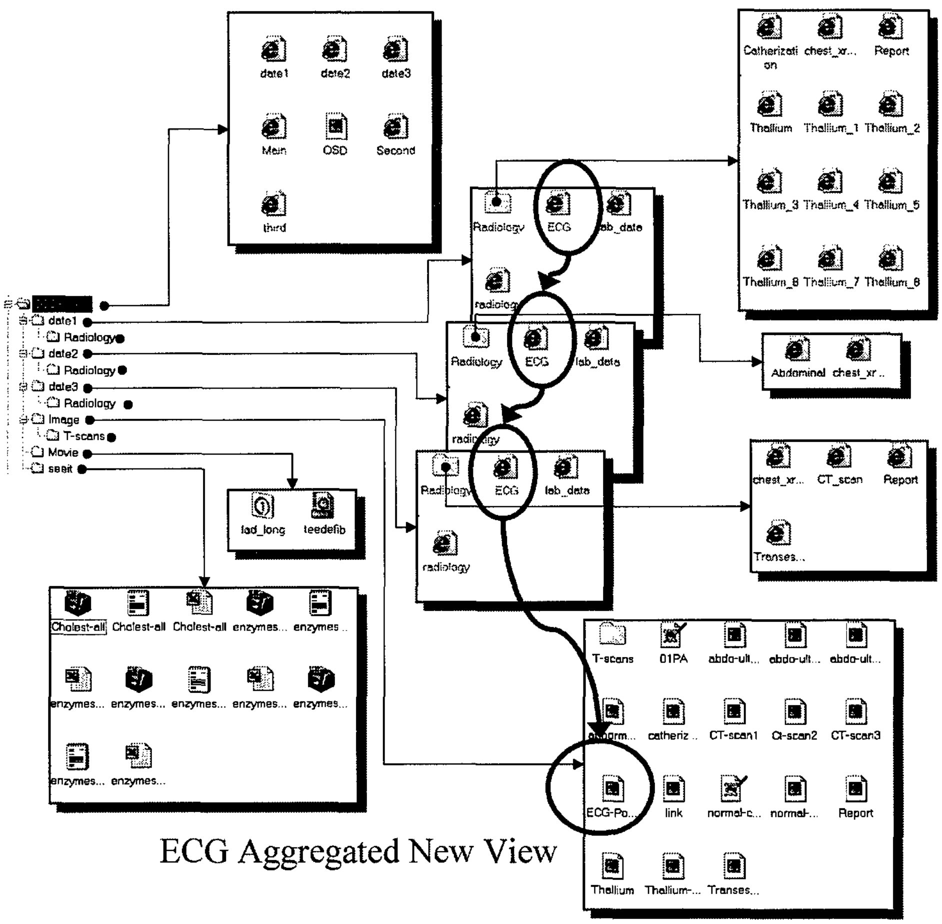

Figure 7. Aggregated ECG view complied from three dates

2.4 Display and Browsing Component

Using the data structure (as described in the previous section), the user can traverse through different presentations and request new presentations. The presentation space is organized around the *Browse3D* Web browsing tool[2].

Browse3D is a next generation web browser that provides a graphical interface for viewing and searching the Web content. Its interface space is organized around a three-walled-room design display interface. The current content is displayed on the center wall, with images of forward links from that page on the right wall, and a graphical history of content browsing on the left wall. The user can pan the three-walled display room, zoom on the content, and flip a wall to see more content presentation. The sidewalls in the BetterView Browse3D based display space initially intially a top-level view of the data (the presentation views) with various hyper-links to facilitate rapid drill-down operations to more specific views (Figure 8).

Figure 9, Figure 10, and Figure 11 depict different views of the *BetterView* interface space.

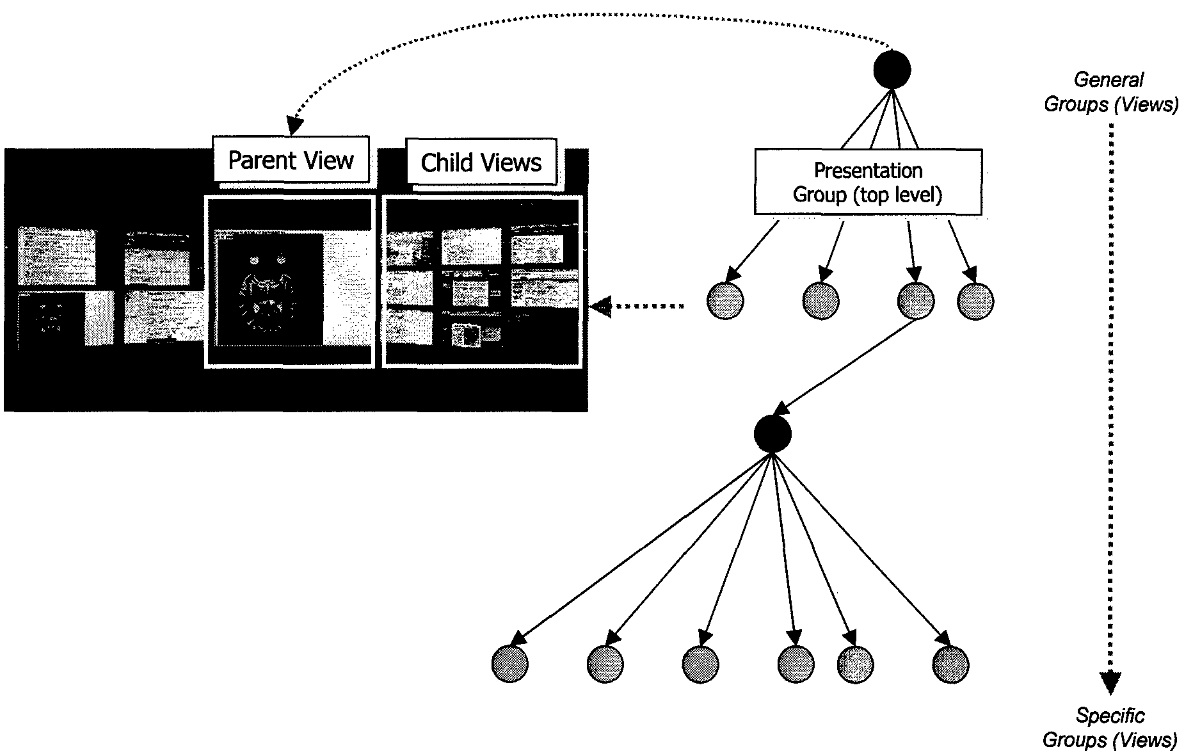

Figure 8. Mapping of data tree structure to the presentation groups/layers

[2] Sigma Systems Research, Inc. has signed an agreement with Browse3D Inc. (Browse3D tool developer and distributor) to co-develop *BetterView*'s display interface. Browse3D, Inc. won Best Internet Software award (for the Browse3D Browser) at the Comdex Fall 2001 Technology Show.

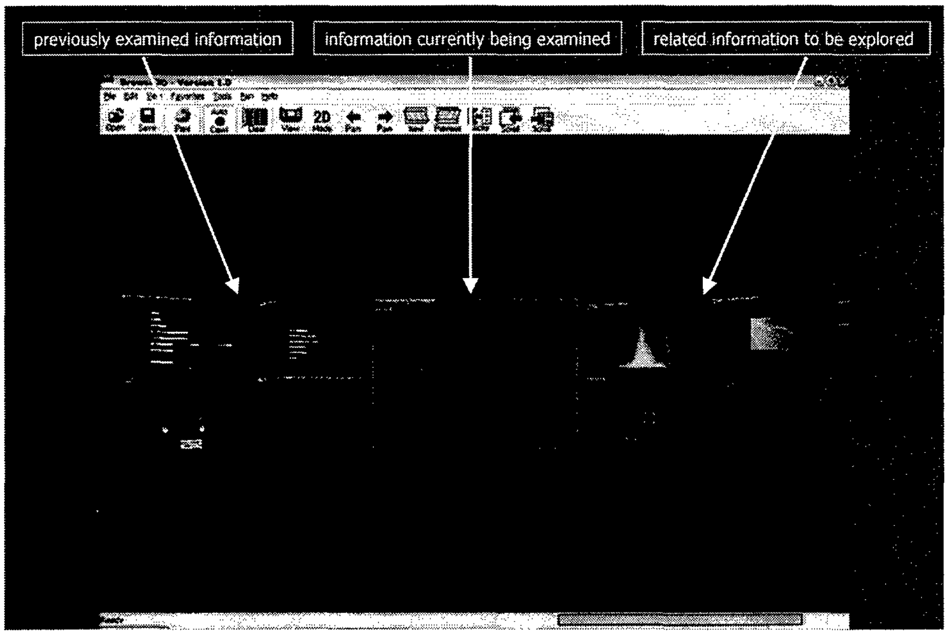

Figure 9. *Browse3D* based interface to *BetterView*

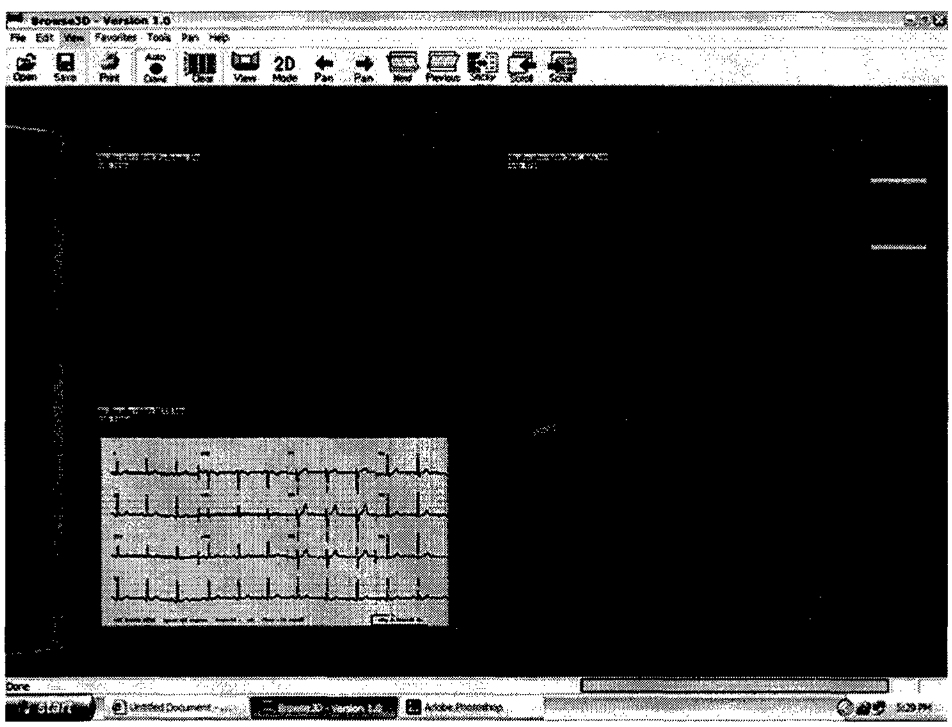

Figure 10. A sample view of the right wall (display of forward links)

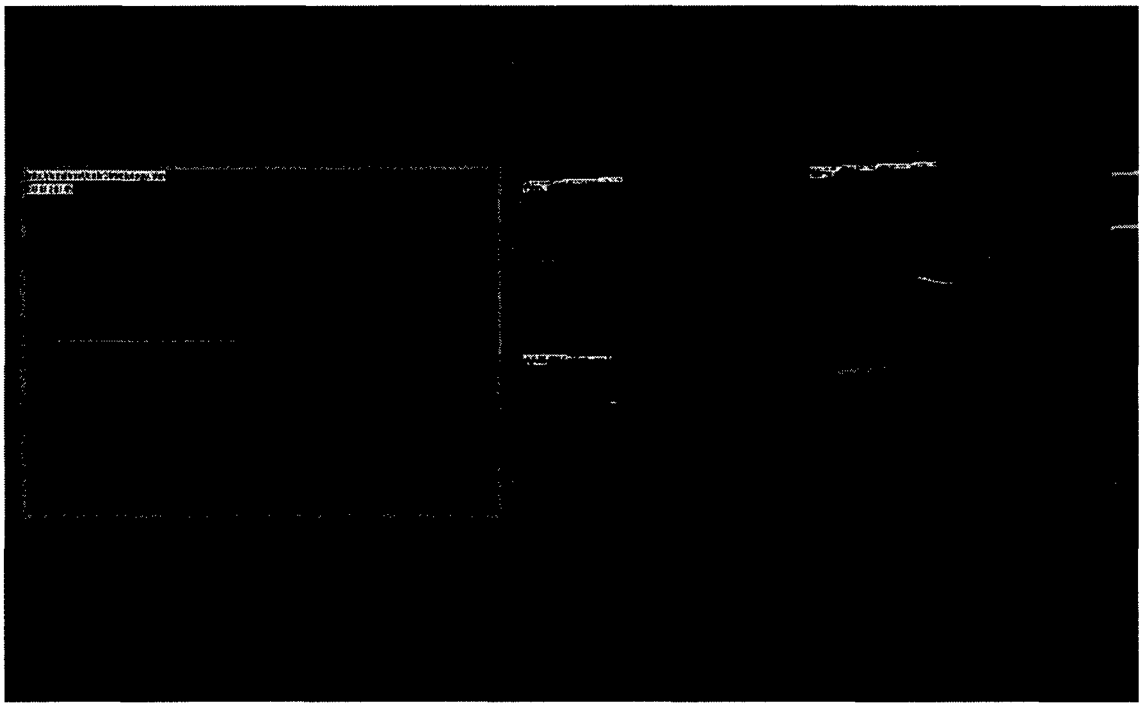

Figure 11. Radiology presentation node with its forward links displayed on the right wall

2.5 3D Visualization Component

A 3D graph visualization approach are in *BetterView* to depict temporal trends. The approach will be based on the Model-View-Controller paradigm of separating an application's data (model) from its visual presentation (view). The visualization component is fully interactive (i.e. enables users to perform spatial operations such as navigation and zoom operations) and is rendered through a Web browser. Interface elements (Controllers) act upon models, changing their values and effectively changing the views. The Model-View-Controller paradigm supports the creation of applications which can attach multiple, simultaneous views and controllers onto the same underlying model. Thus, a single landscape can be represented in several different ways, and modified by different parts of an application. The controller can achieve this transformation with a broad variety of actions, including filtering and multi-resolution, zooming, translation, and rotation.

Figure 13 illustrates the main idea behind the 3D graph generation mechanism. The component provides navigational aids that enhance a user's explorative capabilities (e.g., a view from above provides a good overview of the information, but it is not until zooming in and around and inspecting small items that the user gets a detailed understanding). Specifically, using GUI controls and a mouse the following operations can be executed:

- Landscape Navigation: Using mouse movement and controls the user can change views by zooming on the landscape, rotating around it, and/or translating its display,
- Semantic Zooming: A semantic zooming operation (i.e., a display of textual information associated with a specific lab test) can be performed by "brushing" a given graphical object with the mouse pointer,

- Generation of Multiple Views: Multiple landscapes can be rendered in the visualization space, and
- Linking to Additional Information: Moving the mouse pointer to a graphical object and clicking on it invokes the process of displaying additional information associated with this object.

An example of 3D graphical display is depicted in Figure 12. A historical data set on Cholesterol, LDL, HDL , and drug interventions are projected on a 3D display space.

The Phase I project has initially analyzed incorporation of techniques for automatic browsing in a 3D visualization space. These techniques define a library of operations that the clinician can invoke for automatic execution, e.g., a "walk-through" navigation process that executes the following sequence of commands: zoom on the last MRI, display MRI's region-of-interests and the evaluation report, and proceed to all other data locations that are linked to this MRI). The user can define the "walk-through" instructions by using a simple scripting language. The scripts will also be used for capturing the user's interactions with the system (e.g., in a record mode). The script file can be saved, and later loaded and executed again.

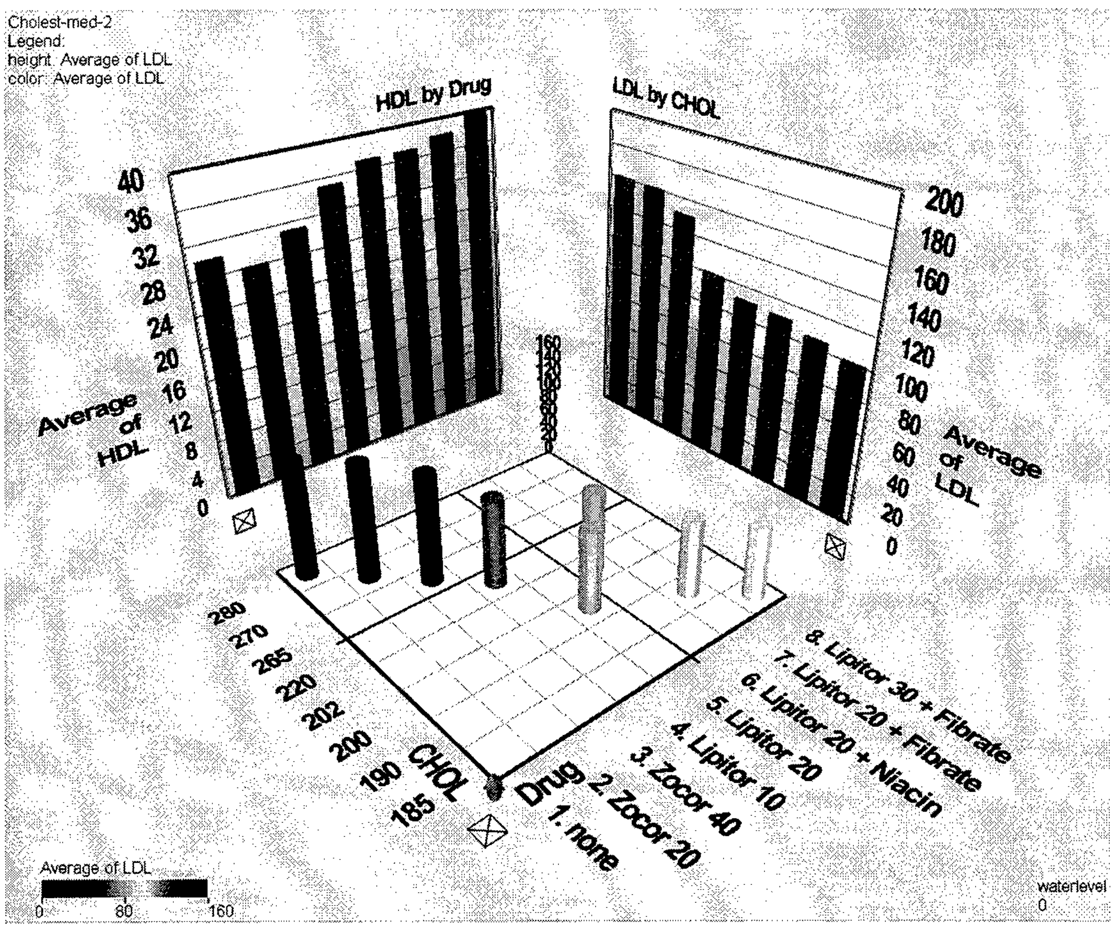

Figure 12. Example of a 3D graphical depiction

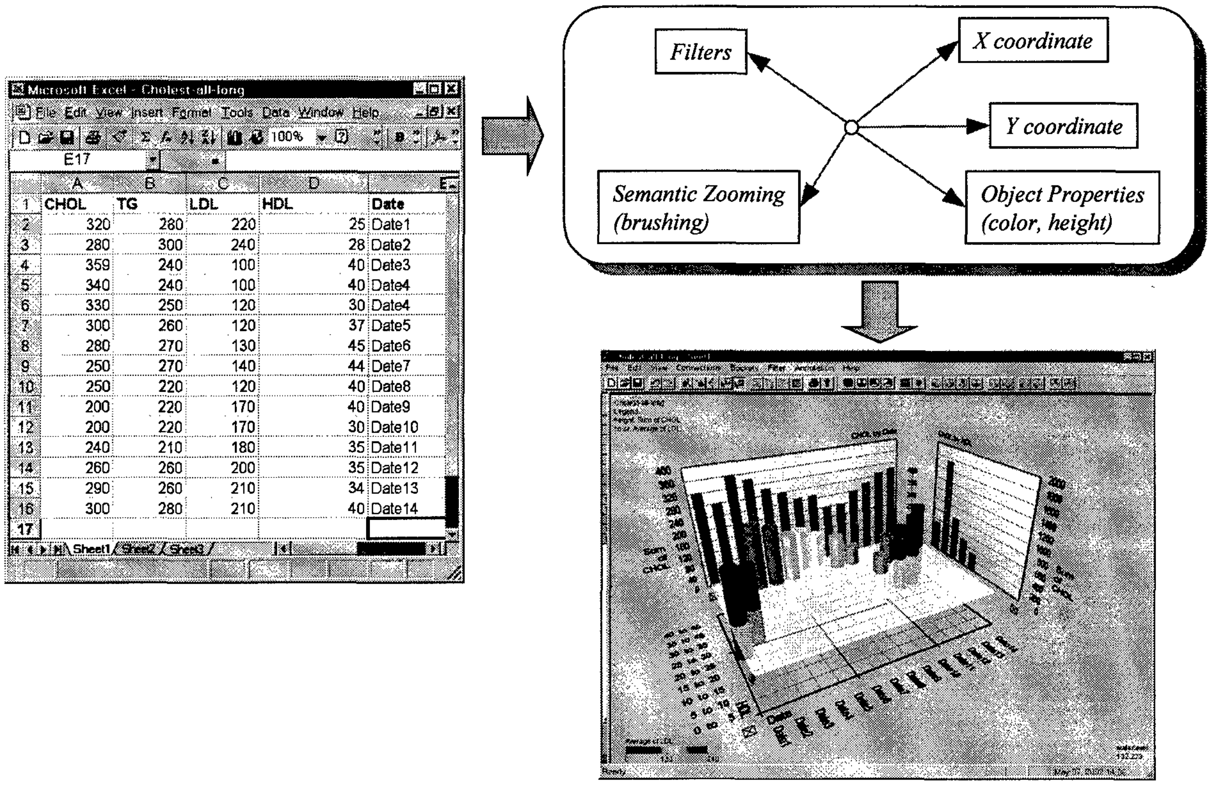

Figure 13. Projecting data onto five coordinates

2.5.1 Library of 3D Visual Landscapes

The Phase I effort has evaluated various 3D landscapes for visualization of medical data. This was accomplished by rapid prototyping of 3D graphical presentations and their subsequent experimental validation. Figure 14 and Figure 15 represent just a few examples of the prototyped landscapes.

Figure 14 depicts a three-parameter temporal correlation space. The parameters, MED1, MED2, and MED3, are projected in 3D and synchronized with the time coordinate. Two time-slider controls are used to cross-link the values represented by the parameters. This general landscape can be used for analyzing various temporal interdependencies in the medical data (e.g., drug interactions in lowering high blood pressure).

Figure 15 depicts a 3D image viewer and represents a utility type of visual presentation. It can be used for spatial organization of stored data. In the presented landscape the medical imagery data is organized according to its acquisition time by a specific medical modality and its volumetric size. The chest x-ray close to the front represents an image thumbnail with very small data size and the other x-ray represents a high resolution image with a large data size.

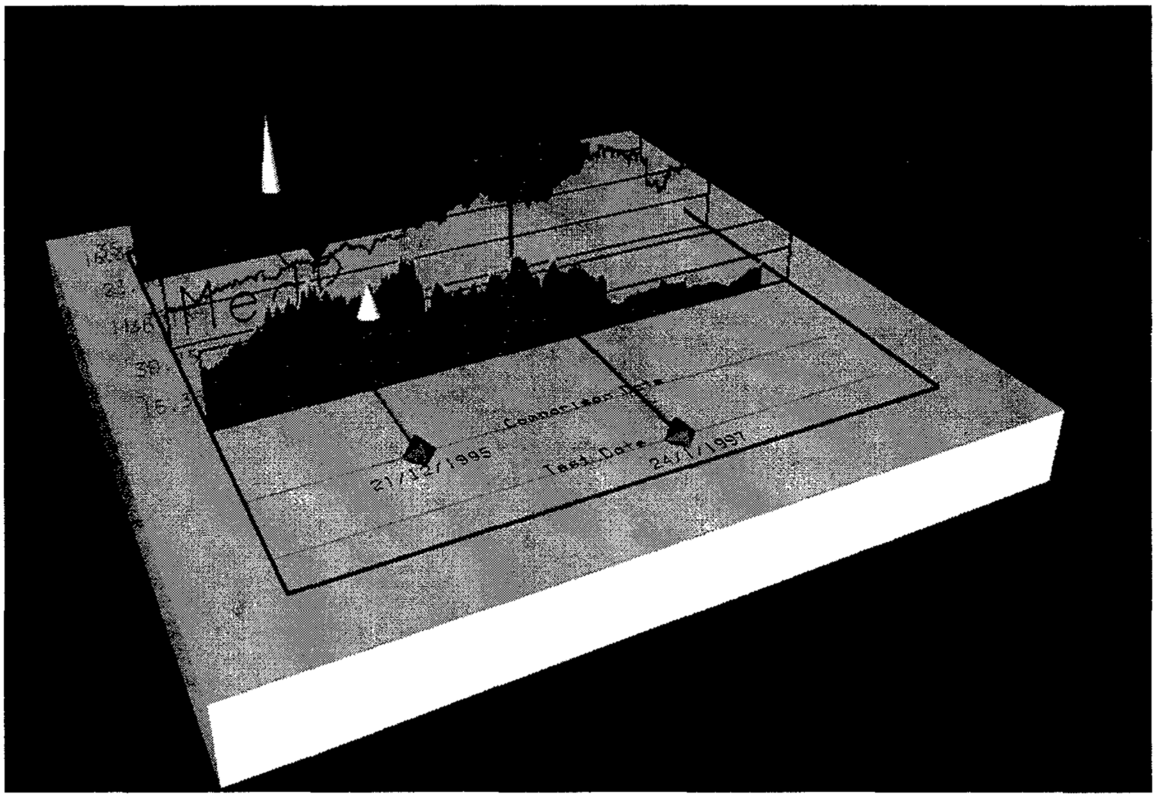

Figure 14. A three parameter correlation space

Figure 15. An imagery viewer

While exploring different visualization landscapes and accessing their applicability to *BetterView*, the Phase I project has developed a set of initial guidelines for prototyping of 3D medical data visualizations. The major five developmental steps defined in the initial version of the guidelines are: (1) Requirements, (2) Understanding, (3) Data Understating, (4) Mapping Data to Visual Layers, and (5) Adding Interactivity. Appendix B these guidelines in greater detail.

2.6 Data Request Modeling Component

This component uses a concept-oriented approach to request data elements. This component will be fully implanted in Phase II.

In a concept-oriented approach to the display of medical information, appropriate *models* of *data requests* are needed in order to determine which data is most likely to be of relevance to a specific situation. For example, if the chief complaint happens to be chest pain, then there is a good chance that the physician might be interested in reviewing the EKG data, among others, if such data is in fact available. On the other hand, the EKG data may not be of immediate relevance if the chief complaint is sore throat.

2.6.1 Data Modeling

What is modeled is *the physician's data/information needs.* We like to know what type of situation (e.g. a particular chief complaint, specific lab data, etc.) may prompt the physician to request additional data and the form of that data (e.g. chest x-rays, EKG, Thallium scans, etc).

What is not modeled is *the physician's cognitive reasoning.* We're not trying to model a physician's diagnostic process and the underlying reasoning. This type of reasoning is very complex and not necessarily needed to determine a physician's information needs. The aim of the proposed system is to assist a physician by providing him/her with the appropriate data during the decision making process. The system is not intended to be a replacement for the physician.

2.6.2 Model Construction

The data request models can be constructed using one of the following approaches:

- *Manual* construction *of the models.* In a manual approach, the physician's information needs are encoded into the system manually. These are usually in the form of rules which can capture the relevancy of each piece of information for a specific situation. This approach is often referred to as a *knowledge-based* or an *expert system* approach. A major disadvantage of such systems is the effort that is required from the humans (e.g. knowledge engineers, subject matter experts, etc.) to input the required knowledge into the system. In addition, the task of capturing the physician's information needs in the form of rules is not necessarily a trivial one. A major advantage, however, is that since the rules are written manually, they are usually pretty accurate. We don't need to rely on the system's intelligence for the construction of sound models.

- *Automatic* construction *of the models*. In an automatic approach, the models are generated by the system itself. This is usually achieved through the use of *machine learning* techniques. The system could learn the models from the examples of situation-information need scenarios (for example those provided by a trainer) or by observing the physician's interactions with the system. Of course, the most significant advantage of such an approach is the little effort that is required from humans. This is especially important for hard to capture knowledge. Here, the models may not be totally accurate and/or complete since they are automatically generated from available information. This is why it is important for these automatically generated models to be expressed in a human comprehensible format. This allows the experts to examine the generated models for accuracy/completeness and to make changes if necessary.

- *A combination of the above approaches*. There are systems that combine the manual and automatic approaches described above. An example of such a system would be a knowledge-based system with learning capabilities. Such systems can initially be provided with only a subset of the desired models (e.g. rule sets). Some of these models may not necessarily be totally accurate in the beginning. The system however has the ability to modify its models by learning from its interactions with the user (e.g. the physician). Again, this is achieved through the use of machine learning techniques.

2.6.3 A learning Approach to Modeling Data Requests

The Phase I project investigated a learning approach to the modeling of data requests. As mentioned previously, the task of capturing the physician's information needs in the form of rules is not necessarily a trivial one. We like to have the system acquire most of the models needed for determining a physician's information needs on its own. In addition, we like our system to be able to adapt to a particular physician's needs/habits. To this end, the system should be equipped with advanced learning capabilities. In a learning approach, previous instances of situation specific data requests (i.e. recorded encounters) are used to build models that can be used for the prediction of data requests in future encounters (Figure 16). The previous instances are referred to as training examples.

Although in theory it would be possible for the system to learn all the data request models on its own (using a good set of training examples provided by a human trainer or coming from existing electronic health records), a more realistic approach would perhaps be that of semi-automated acquisition of such models. In other words, the system is provided with an initial set of rules that are not necessarily complete or accurate. These rules may be generated by knowledge engineers or be input from existing clinical knowledge-bases. The system will then refine this initial rule set overtime through its interactions with the users (e.g. physicians). Figure 17 (A) and (B) depict the automated and semi-automated approaches to the acquisition of data request models.

There are different approaches to learning and the next subsection describes machine learning in more detail.

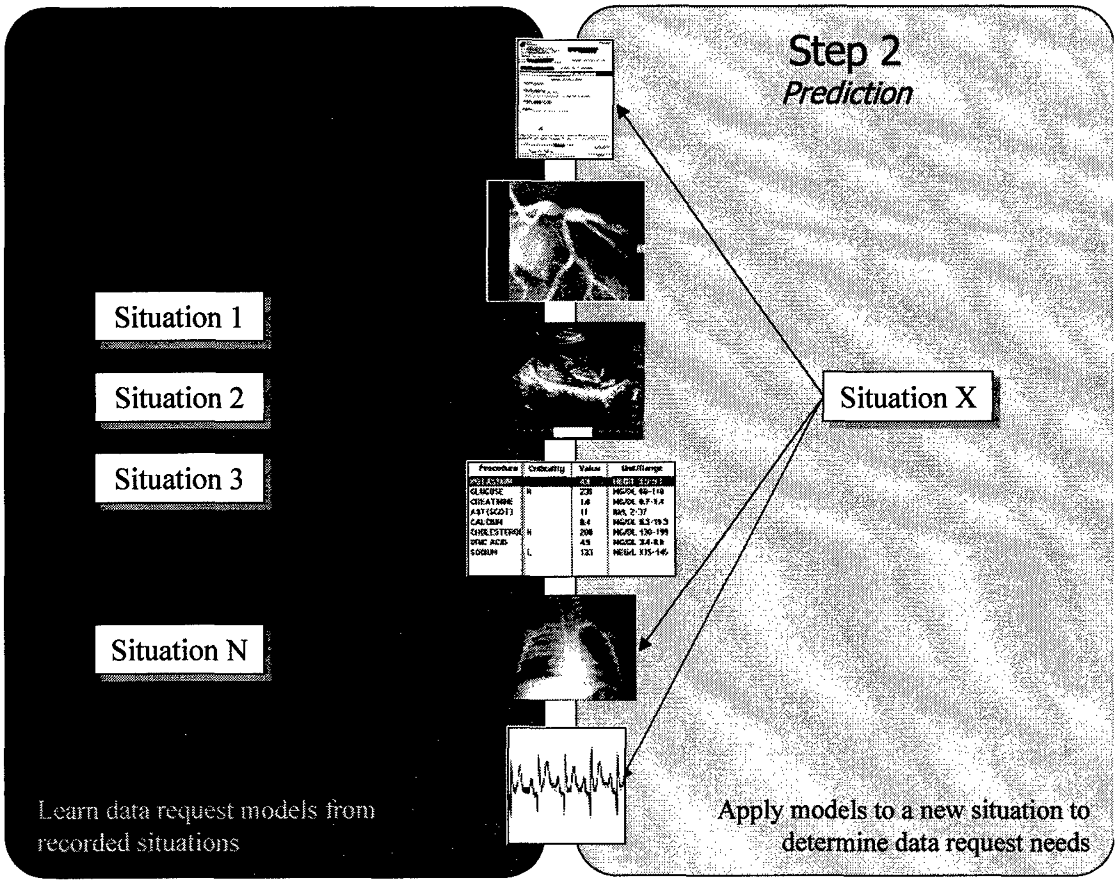

Figure 16. A machine learning model acquisition mechanism

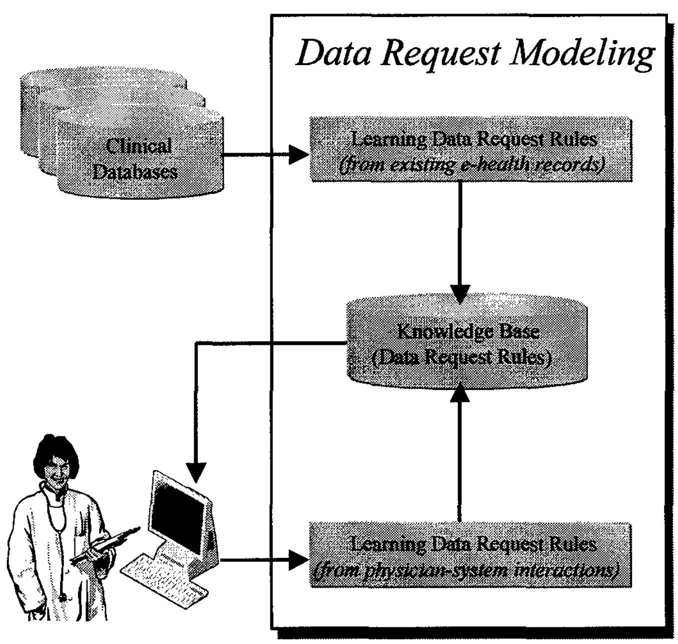

Figure 17 (A) An automated approach

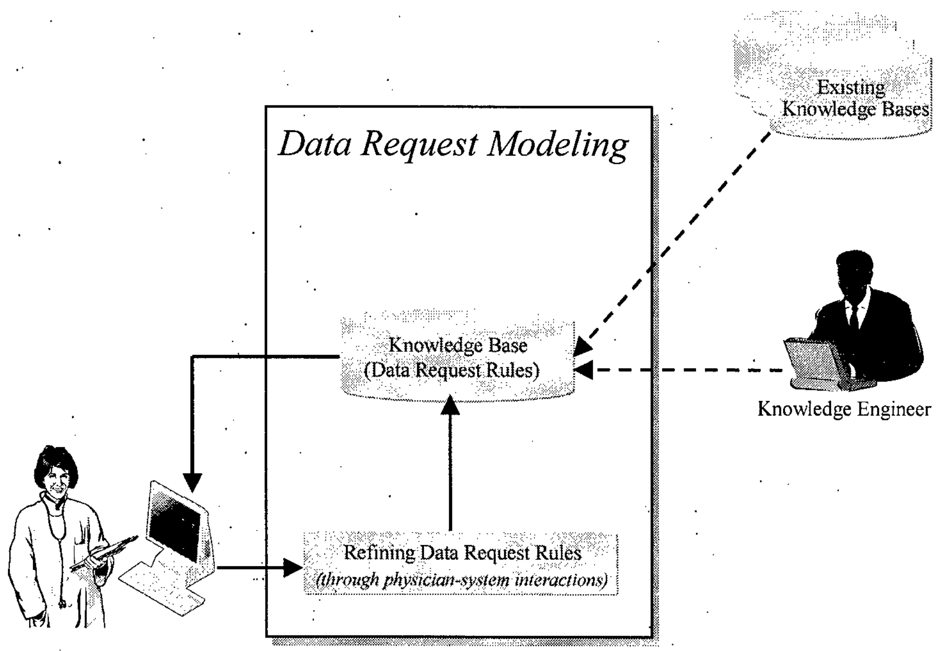

Figure 17 (B) A semi-automated approach

Figure 17. Data modeling approaches

2.6.4 Machine Learning

Learning has always been recognized as one of the fundamental characteristics of any intelligent being. Building computer systems with learning capabilities has been a continuous goal of artificial intelligence. There are many different approaches to learning. These include various types of learning tasks (e.g. concept learning; reinforcement learning), inference mechanisms (e.g. deduction; induction; analogy), computational mechanisms (e.g. decision trees; neural networks; genetic algorithms), and representation spaces/structures (e.g. vector space; attribute-value pairs). Some of the more common learning techniques include:

- *Concept learning*. Concept learning addresses the problem of learning general descriptions of concepts from specific instances of those concepts. In a concept learning scenario, the learning program is provided with positive and negative (i.e. counter) examples of a target concept. Since these examples are provided by a human supervisor for the sake of learning, they are called training examples. The job of the learning algorithm is to come up with an approximation of the target concept by performing an inductive inference on the training data. Most often the inference performed is an inductive generalization. An inductive generalization builds general hypothesis of the target concept, by finding general descriptions which cover the positive training examples without covering the negative ones. The output of a concept learning algorithm is the approximation of the target concept usually in terms of decision rules or decision structures (e.g. decision trees). Previously unseen examples, or testing examples, can then be classified as belonging or not belonging to the target concept (i.e. their class memberships are determined) using these rules or structures. Decision tree and rule learning are among the better known concept learning techniques. The following is a brief description of these techniques:

- *Rule learning.* Rule learning algorithms have been used to generate classifiers in the form of a set of DNF (disjunctive normal form) rules. While decision rules have proven to be as effective as their close relatives decision trees, they have some major advantages such as their compactness and their easily comprehensible representation. DNF rules are generally constructed using a "bottom-up" strategy. At the beginning of the learning process each example may be represented by a single rule with all the attributes as its clause premises and the class as its clause head. The rules are then generalized through an iterative process which removes some of the premises so as to cover as many positive examples and as little negative examples of a class as possible. Sometimes a "pruning" step similar to that of decision trees is also applied to further generalize the rules. Different rule learning algorithms use different heuristics for generalization and pruning.

- *Decision tree classifiers.* Due to their symbolic nature, decision trees are also very suitable for generating class descriptions that are easily comprehensible by people; even though, their representation is usually not as compact as that of decision rule classifiers. Decision tree generation follows a "top-down" strategy. Decision trees classify examples by sorting them down a tree whose leaf nodes provide the classes of those examples. Each node in the tree represents a test of some attribute (e.g. presence or absence of a particular term) and the branches represents the possible values of those attributes. The closer the attribute is to the root (on a given path), the higher its information gain is (i.e. it has more discriminatory power). The bias here is to build shorter trees.

- *Instance-based learning.* An instance-based learning algorithm, unlike a concept learning algorithm, does not try to find approximations to target concepts. Instead, it just simply stores the training examples and puts off the processing till a testing example in encountered. This is why instance-based learning algorithms are also referred to as lazy learners. The class membership of a test example is determined by comparing it to the stored training examples using a similarity/distance measure such as the Euclidean distance. In a k-Nearest Neighbor algorithm for example, the class membership of a testing example is determined by the class membership of its k (i.e. k = 1...n) closest neighbors. The closest neighbors of course are those training examples that have the shortest Euclidean distance to the testing example. Case-based reasoning is another variation of instance-based learning.

2.7 Software Implementation

The implemented software for the *BetterView* suite will constitutes a layered architecture of class libraries and components. Layering is a technique for structuring software by defining and conforming to interfaces between software components. It is distinguished from other software-structuring techniques by the presence of a hierarchy: components at one level interact only with components immediately above or below them. Upon successful completion of Phase II, the BetterView implementation will constitute a Java virtual machine software environment.

Figure 18 depicts a high level view of BetterView interfacing with a CHCS data warehouse (Composite Health Care System). The interface software layer will be implemented in Phase II and will involve building a Java based middleware.

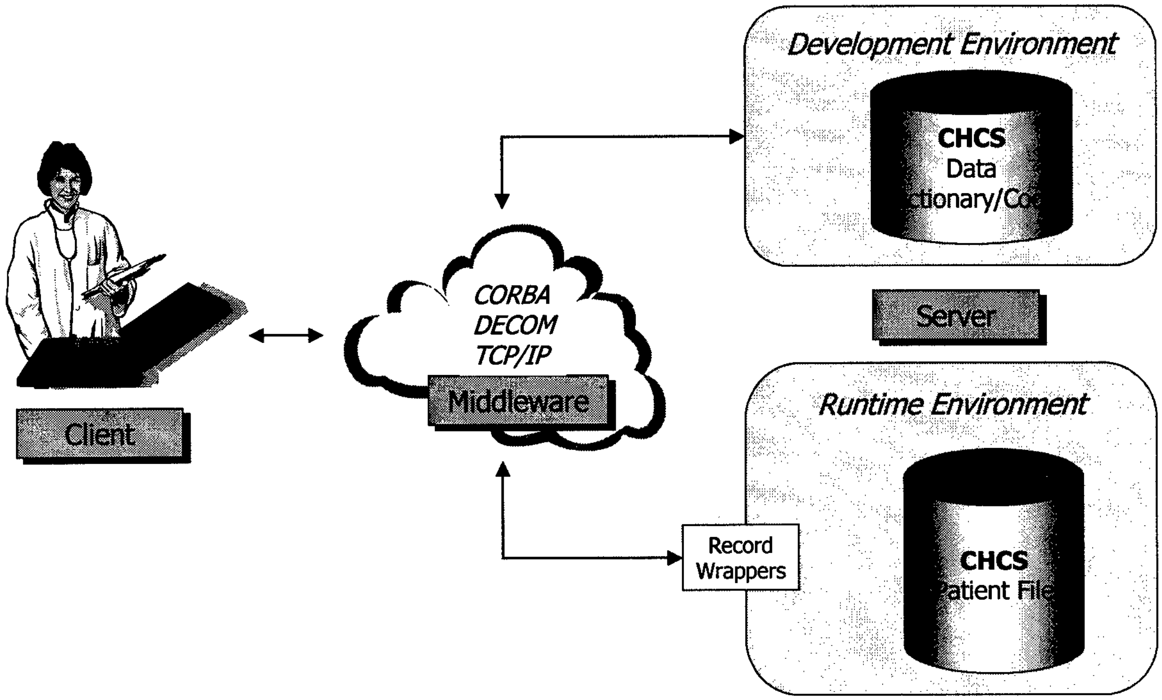

Figure 18. A high level view of *BetterView* interfacing with CHCS

3.0. Related Work

The idea of a computerized problem-oriented medical record has been around for several decades. Dr. Lawrence Weed first introduced the concept some 35 years ago. Of course the idea did not really materialize till the early 90's, when computer-based patient records (CPRs) began to generate much interest among the practitioners. The popularity of these earlier systems were however short-lived. There were huge costs associated with the necessary equipment and the required training which could not be fully justified when the benefits of these systems were carefully analyzed. In addition, the original vision of having a universal medical record for a single individual which can collect data from all the various providers was never realized. Privacy issues of course contributed significantly to the failure of this vision in addition to the various technical challenges.

In recent years, however, the concept of an electronic health record (EHR) has replaced that of the CPR. An EHR (also referred to as electronic medical record or EMR), unlike a CPR, focuses on interoperability of various data repositories of a specific enterprise (e.g. provider organization). The relaxation of the interoperability among various enterprises requirement associated with the original CPRs makes the success of the EHRs much more likely. In addition the EHRs are more or less component-based in nature. Meaning that the focus is on developing the various system components and their associated concepts as opposed to a single system. In addition, the concept of a Web-based EHR resolves much of the problems associated with traditional integration. All of these improve the chances for success.

The fact that we need better mechanisms for handling the patients records is a point that is hardly arguable. Perhaps this is as much true today as ever. The Centers for Disease Control and Prevention identifies medical errors as one of the leading causes of death in this country. A study conducted in 2000 showed the number of deaths attributed to medical errors to be somewhere between 44,000 and 98,000 annually. A significant number indeed. Moreover, the studies also suggest that the majority of these errors are not attributed to individual recklessness, but rather to flaws in health system organization, including information management. The following are a few of the common flaws associated with medical information management:

- Illegible writing in medical records,
- Lack of integration of clinical information systems,
- Inaccessibility of records, and
- Lack of automated allergy and drug interaction checking.

A separate survey conducted by Canadian researchers University of Toronto and McMaster University in 1997 suggested that while 67% of the physicians surveyed felt an electronic patient record system would make their work easier, an even larger percentage – 87% - felt that such a system would result in better patient care.

So where are we today?

The Medical Records Institute's 3rd Annual Survey of Electronic Health Record Trends and Usage reflect the current state of existing EHRs as well as their desired state in the future. According to the survey, the need to improve: the ability to share patient record information among healthcare providers, clinical processes or workflow efficiency, and quality of care were identified as the most important factors driving the need for EHR systems with 83% of those surveyed identifying all three as a major factor. Other major factors were as follows:

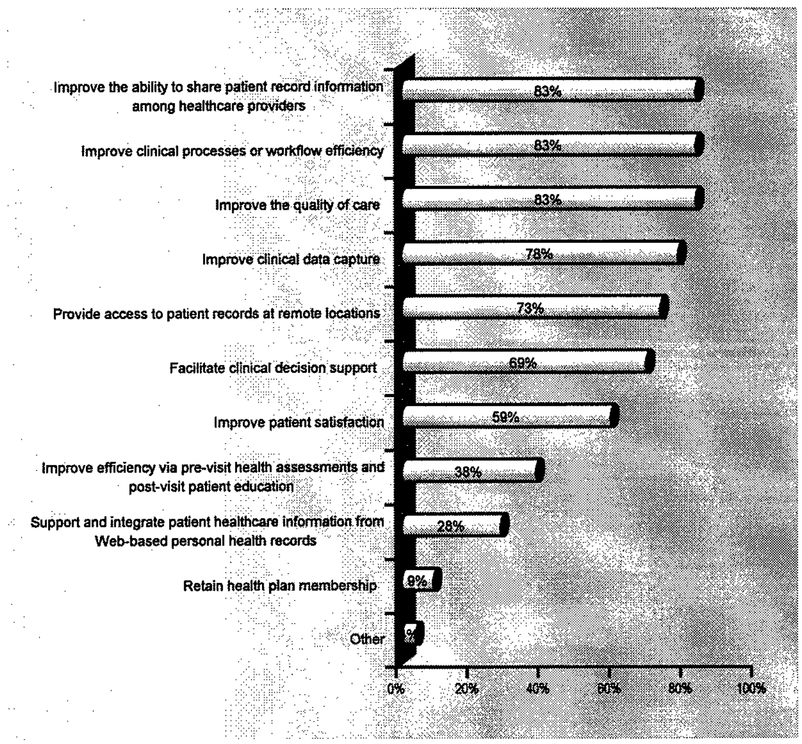

Figure 19. Desired functions for CPR

Figure 19 depicts the respondents' list of the functions desired to be included as part of the electronic patient record system.

In addition, the question on the components of the EHR that are actually in use today reveals that the current state of EHR is far from ideal. While about a third of the respondents acknowledge the existence of a network of some sort, only about 7% are actually utilizing the Web-based EHR. Even components for the storage and handling of medical images doesn't seem to be a major component of today's EHR systems. Figure 20 shows the complete list of the various components and their usage.

Where are we headed?

The Medical Records Institute Survey's question on the components that are expected to be implemented within the next two years suggests that most respondents recognize the Web-based and image technologies as desired components of their system. The summary of responses, depicted in Figure 21, may help us identify some of the key components of the future systems.

The main characteristics of the best available systems

What follows is based on an analysis of the winners of the Computerized Patient Record Institute (CPRI)'s Nicholas E. Davies award for excellence in electronic medical information systems. These, in other words, are known as the "best" available systems. The analysis shows that the best EHR systems have the following functional characteristics:

- All have taken a practical rather than purist view of the EMR
- Incremental implementation; all state they are part way though a long journey
- Each increment focused on overcoming specific barriers to care, rather than nebulous goals such as "creating a paperless process"
- Systems viewed as enablers of clinical practice improvements and business goals rather than a goal unto themselves
- All have resulted in decreased reliance on paper-based sources of information
- Decision support is the largest payback and value added by EMRs compared to paper records

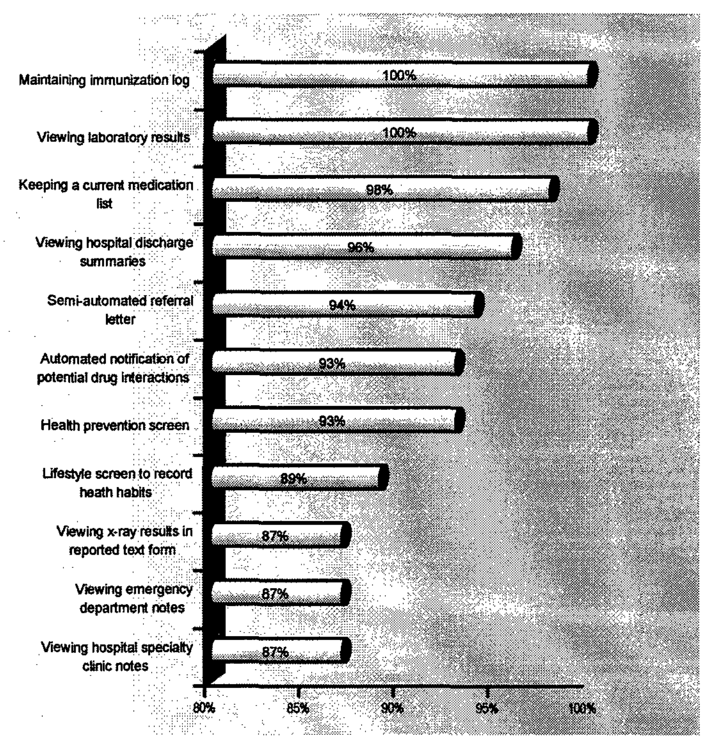

Figure 20. CPR functional component usage

The analysis also reveals that the best systems have the following main technology features among others:

- Wide spectrum of different hardware and software systems,
- A focus on standards-based data architecture rather than specific applications,
- Fast response time,
- Reliability,
- Ease of use, and
- Flexibility to adapt to organizational change.

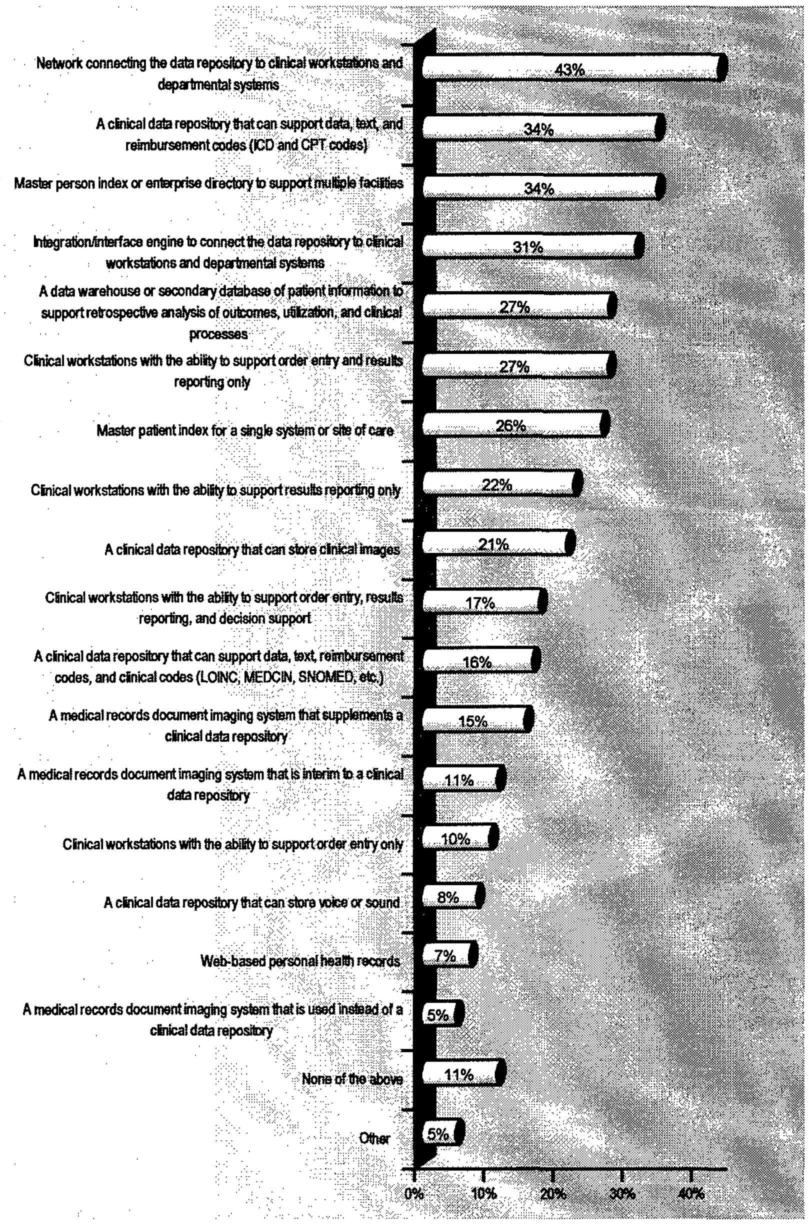

Figure 21. Key future component

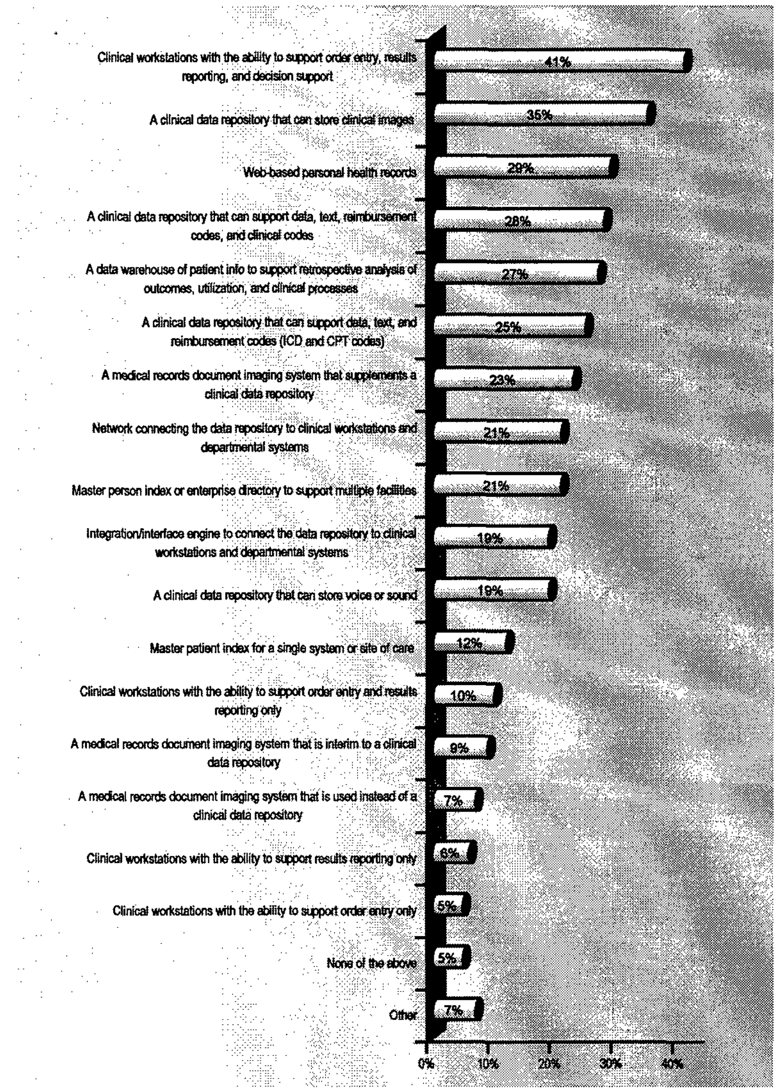

Figure 22. Key future component

Web-based EHRs

The Medical Records Institute Survey of 2001 also reveals a strong desire for Web-based EHRs. According to the survey a good percentage of the systems already incorporate Web-based technologies in many of their components and many more systems will have Web-based capabilities over the next two years. The following are the actual percentages according to the survey.

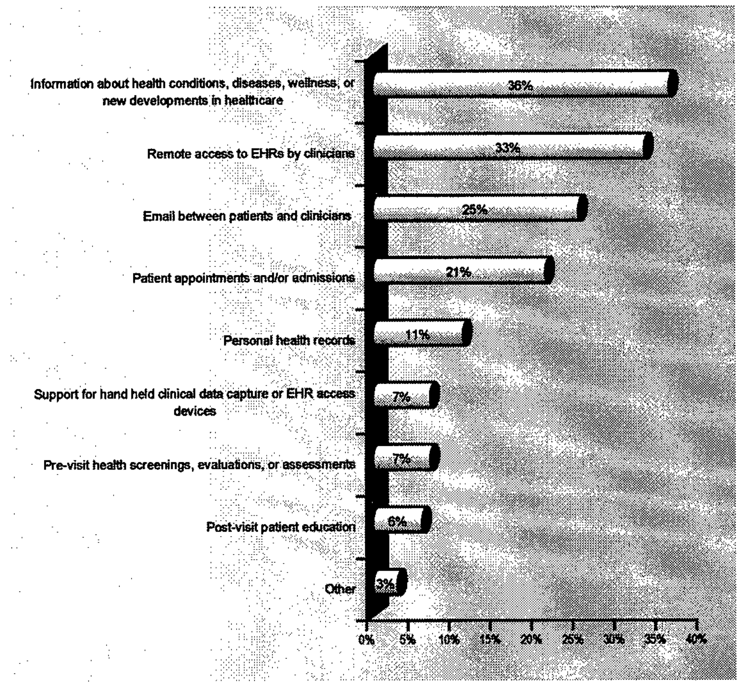

Figure 23. Application installed today

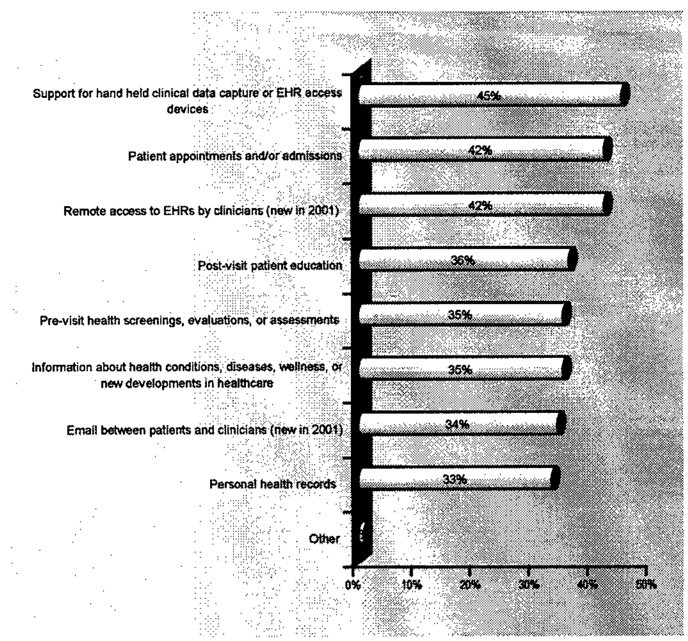

Figure 24. Applications considered for the next two years

4.0 Commercialization Strategy

One of the main tasks in Phase I is the development of the initial commercialization strategy. The following sections describe elements of this strategy.

4.1 Phase I Foundation For Future Commercialization Activities

Phase I developed an initial set of *BetterView* software components. These components will provide a foundation for the construction of the final system and its fielded demonstration. The Phase II reports will include a software description, manuals, and a description of the experimental validation of the Phase II prototype. This documentation will follow elements of the Capability Maturity Model at Sigma's self-assessed level 3.

BetterView software components will follow a component-based software engineering paradigm. Component software engineering extends the earlier software-object model by adding interoperability between applications, facilitating reusability through interface extensions, and allowing remote management from a variety of platforms and languages.

A component-based approach will considerably simplify the integration process. In addition, the component-based architecture of the final system will be more closely aligned with the Advanced Information Technology Services Reference Architecture, and will expedite interoperability, reuse, and rapid transition of software components from this project into other DoD programs. The component nature of the system's architecture will also enable the contractors to add functionality to some modules without altering the overall system design. This will significantly facilitate Phase III activities.

4.2 Commercial Potentials

The commercial potential for this technology will be pursued with the Department of Defense (e.g., TRICARE - the Department of Defense healthcare program for military families and retirees) and non-government healthcare organizations. Specifically, the technologies developed under this SBIR project should be readily applicable to those HMO type healthcare provider commercial sectors that encompass a full range of services from outpatient primary care in remote clinics to intensive care within large teaching medical centers.

The healthcare information system (HIS) industry is currently growing rapidly in various countries, with an expected average future annual growth rate of about 15% over the next years (e.g., in the UK, following Government legislation that requires 35% of hospitals to switch to Electronic Patient Records by the end of 2002, the HIS growth is substantial). The HIS market can be segmented according to end-users and thus splits into hospitals, physician groups and payers/managed care organizations. In the US, IT expenditure in hospitals was about $5 billion in 1997, thus accounting for the largest proportion within the HIS market. With the growth of integrated healthcare networks, the need for clinical data interface systems and open architectures will rise substantially.

4.3 Mission and Objectives

Sigma Systems Research, Inc. will spin off a new company dedicated to the commercialization of the *BetterView* technology. The long-term strategic mission for this spin-off company is to be the leading world provider of clinical data display solutions (products and services) to government and private organizations and enterprises. The short-term primary mission is to sell and install beta versions of the developed *BetterView* toolbox on the customer sites in order to lay the foundation for the future success of repeated installations.

The spin-off company will seek an investment of up to 1.5 Million dollars to:

- Deploy the marketing and sales teams,
- Build the infrastructure of support for marketing and sales personnel,
- Establish a solid customer base,
- Enhance the product,
- Sell the *BetterView* technology and its intellectual rights from Sigma to the spin-off company, and
- Transition the seed investment to a profitable exit/roll-out within 2 years.

The strategic objectives for the company are to:

- Successfully launch the *BetterView* toolbox,
- Establish beta testing sites,
- Introduce the name and increase its recognition in the marketplace, and
- Develop the first vertical applications and start penetrating their related markets.

4.4 The Development Team

The project will be a collaborative effort of Sigma Systems Research, Inc. (SBIR company) and the following development and commercialization partners[3] (Figure 25):

- Information Pathwaves, Inc. (IPI). Sigma will retain IPI to launch the product marketing campaign. IPI, a Maryland based company, is experienced in the following areas: strategic planning (marketing plans and strategies), sales plans, strategies and tactics, customer positioning, product marketing, and corporate identity packaging.
- Tecmasters (TM). TM will help Sigma in the multimedia and 3D visualization areas during the Phase II developmental effort. Tecmasters' multimedia division has a top-notch team of multimedia designers in computer animation, 3D computer modeling, interactive multimedia, and graphics. Tecmasters developed several interactive

[3] Intend letters of in-kind support are provided with the proposal.

programs for the US Army Corps of Engineers, the US Navy Civil Engineer Corps Officer School, the Command and General Staff College at Fort Leavenworth, and the US Army Aviation and Missile Command).

The project team's strength is in the intelligence, commitment and diversity of its members and in Sigma's working environment that nurtures creativity and innovation. Sigma has always been willing to take risks associated with innovative ideas. It is breaking with traditional thinking that propels paradigm shifts in individuals and revolutionary advancements. We have found that providing such an environment has attracted leaders in diverse fields. It is this unique mix of talent, skills and knowledge that has produced the intellectual critical mass posed to bring the SBIR project (in post Phase I project) from R&D effort to successful commercial products.

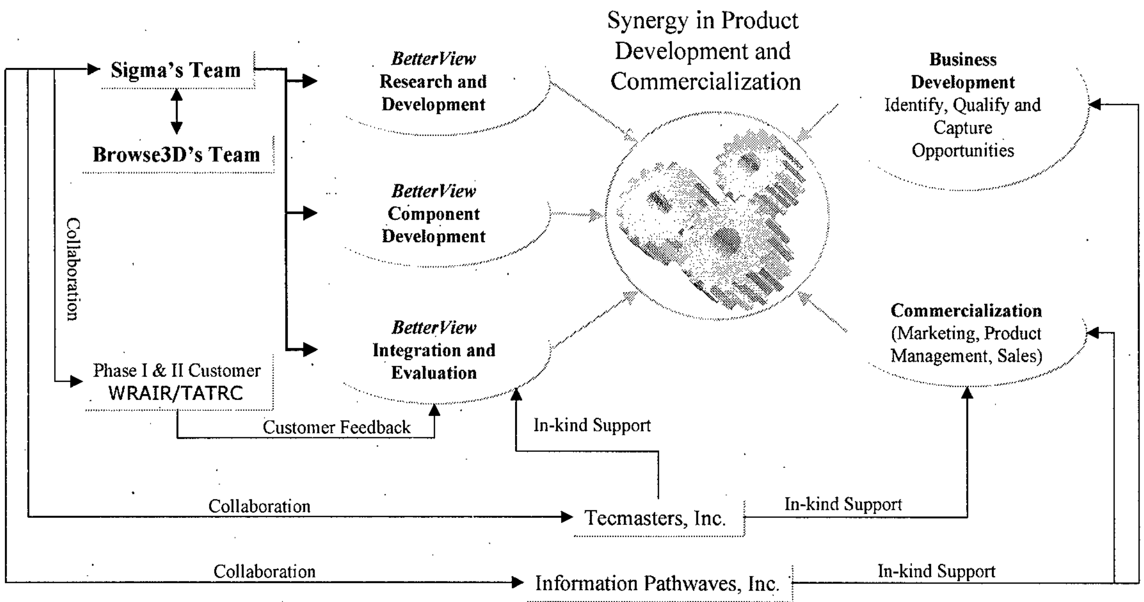

Figure 25: Development and commercialization team

4.5 Strategies

4.5.1 Marketing Strategy

The marketing strategies will focus on communicating the possibilities for value creation that the new *BetterView* technology offers. It will be campaigned on the following strategies:

- Educational. The strategy will seek to create demand for *BetterView* suite of products among broadest possible set of decision makers in various medical and health provider organizations, by communicating the possibilities for value creation that the developed technology provides to potential users and, to provide a clear technology solution to the technology professionals charged with such technology.
- Market-Driven. The spin-off company will target key vertical markets, each of which can benefit very significantly from the developed technology, and on which most of its marketing resources will be focused.

- Strategic Relationships. The strategy will employ various types of strategic alliances with major market players who have large customer bases into which they sell products that are complementary to the *BetterView* products.

The following are specific marketing objectives:

- Penetrate vertical markets with tailored applications and customer benefits by selling industry templates and professional services customized to meet customer requirements.
- Position company's solutions with key decision makers and influencers.
- Sell the developed technology's key differentiators.
- Emphasize the developed technology's feature-rich capabilities and ease of use.

An important aspect of the marketing campaign will be to convey decidedly the principal competitive factors of the *BetterView* technology. The use of advanced proprietary algorithms and component based architecture are example of competitive factors.

4.5.2 Sales Strategy

The sales strategy will focus on building direct sales infrastructure force with a comprehensive support that includes pre-sales consultants, software engineers and analysts, on-site project managers, installation technicians and maintenance support. The direct sale infrastructure will have close relationships with indirect channel partners. This arrangement will facilitate rapid acquisition of market share. By using indirect sales channels, the company will obtain favorable product recommendations from leading systems integrators, applications developers and platform partners, thereby increasing total market coverage.

The sales force will target the following customer groups:

- Value-Added Resellers. VARS will resell the *BetterView* solutions (e.g., traffic flow prediction) bundled with their own enterprise systems. VARS will constitute those software companies that will develop or customize their proprietary software specifically for use with the developed products. VARS will purchase the BetterView products (e.g., toolbox's components) and will incorporate them within their applications software and resell the systems to end-users.
- Value Added Dealers. VADS, or value added dealers, are typically direct sales organizations that sell primarily into a single vertical market and incorporate appropriate specialized third-party software with the company's products for sale to their customers.
- System Integrators. The company will enter into agreements with system integrators to provide training, support, marketing and sales assistance to a number of systems integrators. Systems Integrators include much larger systems customized for use by the federal government and large commercial clients.
- Platform Partners. The company's platform partners will include firms which co-sell and co-market complementary technology to the same target customer base.
- Consulting. The company will be creating a consulting practice to enable ongoing customers to maximize the value of their investment, as well as a support function to

ensure that current customers have access to the company's field engineering and tele-support.

The key sale objectives will include:

- Adaptation of market driven strategy rather than product driven strategy. A well-defined application profile will be complied for each targeted vertical market. By concentrating on the application, and by building in to the product ancillary features to enhance its capabilities, the company will demonstrate a commitment to each targeted/specific business segment. The three key reasons for niche marketing will be: simplification of product requirements, strong word of mouth, and early ability to achieve market leadership.
- Customization. In the initial market-targeting phase, the company will focus on specific customers and customer characteristics (end-users).
- Development of value proposition for each targeted customer market segment. There are three criteria for a must-have value proposition: (a) it enables a previously unavailable strategic capability that provides a dramatic competitive advantage in an area of prime operational focus (b) it improves productivity on an already well-understood critical success factor and (c) it significantly reduces current total overall operational costs.
- Identification of potential users of high-tech products to market *BetterView* capabilities and benefits. The focus will be on technology conferences or forums to identify potential early adopters. The company will establish relationships with potential partners at industry forums. It will also focus on industry standards, application needs and business benefits.
- Education. Educate the potential users on the benefits of movement prediction to create market demand, with specific emphasis on applications and business benefits, ease of use, cost reductions, increased revenues, and better decisions.
- Differentiation. Differentiate the developed technology from major competitors.
- Benefits. Position key benefits, such as (a) integration of decision making analysis with 3D visualization, (b) easy to use, yet powerful, (c) fast response and overall efficiency, and (d) accuracy and quality.
- Marketing channel. Develop specific channel marketing programs.
- Co-marketing. Implement co-marketing partnerships and strategic alliances.

Appendix A: 3D Rendering Mechanism

A.1 System Interfacing

3D visualization is implemented in *BetterView* using SeeIt tool. The tool is based on In3D - a cross-platform class library designed to enable the creation of interactive 3D visualizations of complex information spaces (In3D is supported by Visual Insights Corp.) Since the use of this library is pivotal in implementation of the current and future *BetterView* visualization environments, the next section explains In3D in greater detail.

A1.1 In3D Visualization Class Libraries

In3D implements the Model-View-Controller paradigm of separating an application's data (model) from its visual presentation (view). Interface elements (Controllers) act upon models, changing their values and effectively changing the views. Such a paradigm supports the creation of applications which can attach multiple, simultaneous views and controllers onto the same underlying model.

In3D is designed as a layered class library. It consists of three main layers: foundation, core and extensions. The lowest layer is called the foundation layer, and consists of fundamental functional components of the entire library. In addition the foundation layer also consists of:

- A cross-platform rendering library called Orca. Orca is a VRML 2.0 compliant rendering library. Orca sits atop OpenGL for high performance and accurate rendering and further more it takes full advantage of the available hardware acceleration.

An interpreter for run-time expression evaluation. The purpose of this interpreter is to allow one to perform scenario analysis, predictive and sensitivity analysis, etc. The built in expression evaluator can process the input and pass it onto other parts of the application which can evaluate the expression against existing data.

- A schema mechanism for structuring data - schemas are ordered collections of objects used to describe the layout of data. Schemas allow data models to be programmatically constructed and queried.
- A thread library to enable the creation of multi-threaded applications as well as to make use of multi-processor systems.
- A command mechanism enabling the encapsulation of units that can be attached to interface elements.
- The core layer of the In3D class library can be divided into two principal classes of objects: those which are used to hold data (Models) and those which are used to

provide a visual representation of the data (Views). Other classes include containers, frames, mappers, sensors and controllers.

- Models - In3D structures information as models, classes which use a schema to describe their contents. Models can be constructed dynamically, or read from files. Models are attached to views and store the data to be represented by the views.
- Views - Three principal view types are provided: single, multi and compound. Single views implement a single geometric form. Multi views group multiple single views together, while compound views are aggregates of single and multi views, encapsulating their behavior and exposing a single interface.
- Containers - Containers are classes which contain objects, usually models. In3D provides a number of built-in container classes, the principal type of which are arrays. One, two and three dimensional arrays are provided.
- Frames - Frames are used to lay out and manage scene components in a visualization. They are 3D in nature, existing as a bounding box around their children. Scene components can be views, controllers, sensors, and even other frames. This hierarchy of frames defines the visualization and is rooted in a landscape.

A1.2 Rendering Mechanism

The visualization component implements the Model-View-Controller paradigm of separating imagery data (model) from its visual presentation (view). Interface elements (Controllers) act upon models, changing their values and effectively changing the views (Figure 26).

The Model-View-Controller paradigm supports the creation of applications which can attach multiple, simultaneous views and controllers onto the same underlying model. Thus, a single landscape (imagery and objects) can be represented in several different ways, and modified by different parts of an application. The controller can achieve this transformation with a broad variety of actions, including filtering and multi-resolution, zooming, translation, and rotation. The component provides navigational aids that enhance user's explorative capabilities. Specifically, using GUI controls and a mouse, the following operations can be executed within *BetterView's* visual interface:

- <u>Landscape Navigation</u>: Using mouse movement and controls, the user can change views by zooming on the landscape, rotating around it, and/or translating its display.
- <u>Semantic Zooming</u>: A semantic zooming operation (i.e., a display of textual information associated with a specific MSP) can be performed by "brushing" a given graphical object with the mouse pointer.
- <u>Generation of Multiple Views</u>: Multiple landscapes can be rendered in the visualization space.
- <u>Linking to Additional Information</u>: Moving the mouse pointer to a graphical object and clicking on it invokes the process of displaying additional information associated with this object.

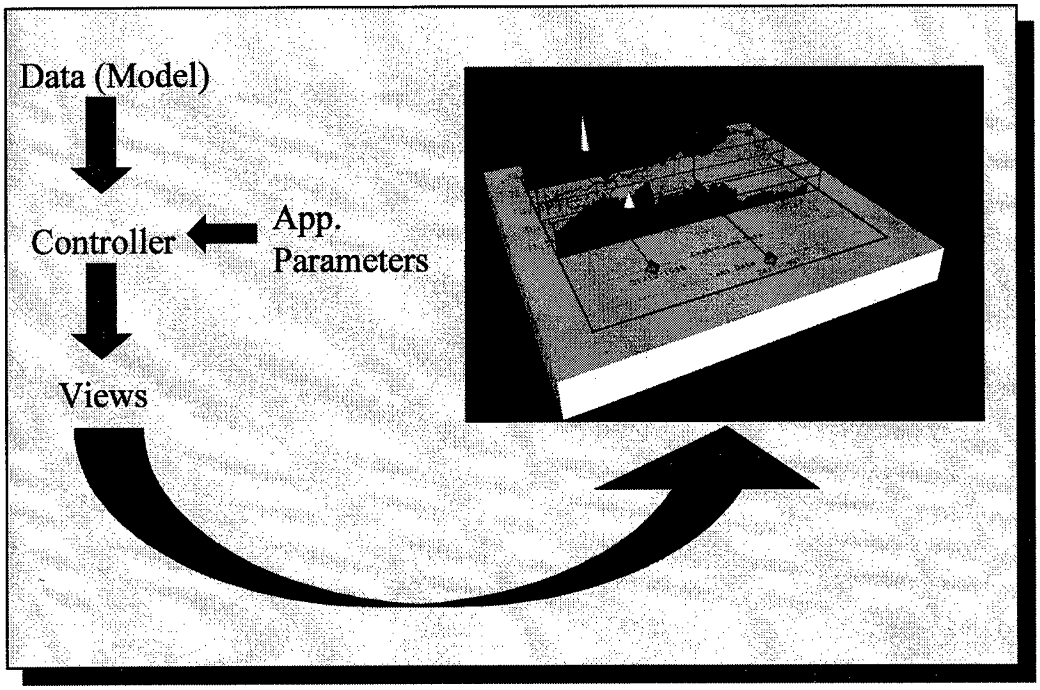

Figure 26: A Model-View-Controller display paradigm

Appendix B: 3D Presentation Guidelines

The following steps are considered in prototyping of 3D visual presentations:

Step 1: Requirements

<u>Decision Requirements:</u>

What diagnostic/prognostic clinical decisions will be made using a specific visualization (historical case retrieval, trends, causal relations. etc)?
What answers must visualization provide to the clinician?
What information is needed to make those decisions?

- Numerical information (e.g., lab work results)
- Unstructured information (e.g., lab work result textual reports)
- Imagery
- How much control over the medical data does the clinician require to form decisions?
- Drill down into details
- Filter out unwanted events/incidents (e.g., unrelated symptoms)
- Run animation

<u>Communication requirements:</u>

Who will use the visualization display?

- General practitioner
- Specialist
- Other user

What information is conveyed to others?
How this information will be conveyed it (e.g., embedded in an email message)?

<u>Information requirements:</u>

What supplementary information do the clinician require?

- Static data to support visualization scene (e.g., color schema)

In what form it will be provided?

<u>Workflow requirements:</u>

How will the clinicians interact with the application?
What steps will they follow to make a decision?

What workflow is currently implemented in other medical display systems (e.g., in CPRs with visualization GUIs)?

- Is it efficient?
- How will the application mimic the workflow
- How will it introduce efficiencies into the workflow?

Step 2: Data Understanding

<u>Where is the medical data coming from?</u>

Many sources including databases, real-time feeds, or flat files (e.g., CHCS II)
From a database or real-time feed,
An interface to get the data into the application?
What is the connection bandwidth (e.g., depending on the size of the CPR database and the complexity of the query, an SQL query can take minutes to complete)?

<u>Is the data source appropriate?</u>

A flat file (e.g., for an explicit set of data), a database (e.g., for data/documents taken from a large repository), XML.

<u>What core data is required?</u>

How will core data be visually represented in the application? Is the data complete and organized efficiently?
What constitutes core data?

<u>What non-core data is required?</u>

Non-core data is data needed for laying out the landscape, providing labels and legends, populating pick lists in dialog boxes and so on.

<u>What calculations must be made?</u>

Not all the information in the medical visualization will necessarily be provided by the data source. If calculations must be made, how much time and system resources are required?

Step 3: Data Organization

The data model is the set of data structures that hold and organize incoming data so that it can be access accessed by the medical visualization Application Programming Interface (API). If the application acquires data from several sources, common data structures should be used. Data categories considered for the medical display applications ate listed below:

- Continuous: Data is differentiated by some scalar value such as time (time-stamped lab results data).
- Discrete/contiguous: Data is divided into discrete buckets, which may or may not be contiguous. These buckets can be used to form a hierarchy, either merging buckets together or splitting them apart.
- Classification: An external classification can be applied to the data such as diagnostic categories, or a kind of referencing scheme not explicit in the data.

- Hierarchy: E.g., hierarchical classifications (category, subcategory, group).

Step 4: Mapping the Data into a Visual Layout

There may be several different ways to view the medical data, each of which may contribute to a specific clinician-patient encounter. Subjective issues, such as color, symmetry, and lighting typically the domain of graphic designers and illustrators, become important considerations (two visualizations, using exactly the same shapes and position, but with different color and lighting can evoke very different reactions from clinicians). The central mapping guidelines is simplicity, i.e., choosing a simple color scheme, coloring important views with bright colors, placing key information in a central location, grouping views of related medical data, using concepts the clinician understands, providing secondary information with subtle colors, representing closely related data in a single view.

Step 5: Adding Interactive Capabilities

This step is concerned with:

- Navigational aids (e.g., presentation scripts that can simplify interaction with a visual display)
- Drill-downs
- Animation playback functionality for time-based data. Visualization should be able to play back data, with controls to start, stop, fast forward and rewind (e.g., easy access to large sets of data).
- Filtering
- Access to the underlying data

DEPARTMENT OF THE ARMY
US ARMY MEDICAL RESEARCH AND MATERIEL COMMAND
504 SCOTT STREET
FORT DETRICK, MD 21702-5012

REPLY TO
ATTENTION OF

MCMR-RMI-S (70-1y) 10 Jun 03

MEMORANDUM FOR Administrator, Defense Technical Information Center (DTIC-OCA), 8725 John J. Kingman Road, Fort Belvoir, VA 22060-6218

SUBJECT: Request Change in Distribution Statement

1. The U.S. Army Medical Research and Materiel Command has reexamined the need for the limitation assigned to technical reports written for this Command. Request the limited distribution statement for the enclosed accession numbers be changed to "Approved for public release; distribution unlimited." These reports should be released to the National Technical Information Service.

2. Point of contact for this request is Ms. Kristin Morrow at DSN 343-7327 or by e-mail at Kristin.Morrow@det.amedd.army.mil.

FOR THE COMMANDER:

Encl

PHYLLIS M. RINEHART
Deputy Chief of Staff for
Information Management

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ADB263653
ADB282255
ADB262232
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